Health Canada Santé Canada

FINAL REPORT
EVALUATION OF THE LABORATORY CENTRE FOR DISEASE CONTROL

October 1993

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Evaluation Report:
Laboratory Centre for Disease Control
Health Protection Branch

Program Evaluation Division
Program Audit and Review Directorate
October, 1993

chronology

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December 1992	draft report prepared for internal review
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executive summary

Introduction

The executive summary presents the findings and conclusions of the evaluation of the Laboratory Centre for Disease Control (LCDC) of the Health Protection Branch. The evaluation included all activities of the Laboratory Centre for Disease Control - with the exception of the activities related to the surveillance and control of AIDS. This report refers to the Laboratory Centre for Disease Control as LCDC, the Program or the Centre.

This is the second formal evaluation of LCDC. It was first evaluated in 1984-85. Since then, LCDC had also commissioned a number of external reviews of its programs and operations.

Evaluation Issues and Questions

The evaluation addresses 18 specific questions covering the following seven general issues: 1) the role of LCDC, 2) risk assessment, 3) the relevance and the quality of expertise and services provided to clients and partners, and the level of expertise developed and maintained by LCDC, 4) the extent to which LCDC fulfils the expectations of its clients and partners, 5) technology transfer, 6) cost-recovery, and 7) alternative organizational arrangements. The list of evaluation questions is presented in Appendix A.

Evaluation Approach, Information, Scope and Limitations

The evaluation uses a systems analysis approach and qualitative methods. The systems analysis is used in examining the role and mandate of LCDC and identifying any significant gaps and overlaps in the Canadian system. This involved developing a conceptual framework, and a "generic" model for a disease surveillance and control system, and a corresponding model of the Canadian system, and examining the current functions and activities of LCDC within the context of these models.

LCDC has no direct responsibility for health care delivery program, or regulations designed to reduce health risks, apart from the administration of the Quarantine Act. LCDC influences the health of Canadians through programs and regulations of other agencies. Therefore, it is not possible to directly measure (or estimate) the contribution of specific LCDC initiatives to the improvement of the health status of Canadians. However, it was possible to evaluate the Program using inductive and/or qualitative methods.

The evaluation conducted five case studies which examined the role of LCDC and the impact of its activities on the disease surveillance and control system. The results of these studies were used throughout the evaluation. The case studies included: 1) Domoic Acid Food Poisoning, 2) Food-Borne Infections, 3) Office of Bio-Safety, 4) Canadian Hospital Injury Reporting and Prevention Program, and 5) Tuberculosis.

The evaluation is based on program and other documents and published literature, and consultations with clients and partners of LCDC as well as program officials. Consultations were also held with officials of US Centers for Disease Control in Atlanta.

The clients and partners of the Program included members of various LCDC committees, provincial* epidemiologists, heads of provincial public health laboratories, TB control directors, and representatives of selected voluntary organizations, officials of Health and Welfare Canada (outside the Program), and researchers in the health field. None of the categories of clients had more than a dozen individuals.

A total of over 140 persons were consulted for the evaluation. These included about 85 clients and stakeholders outside Health and Welfare Canada, over 20 Program officials, 20 persons from HWC but outside the Program, and about 15 from CDC.

A master protocol was designed for consultations. Not all questions in the protocol were applicable to all types of clients. For example, questions related to the running of laboratories were only applicable to the members of the Technical Advisory Committee and laboratory personnel. However, some questions such as, client expectations, what role should LCDC play, etc. were discussed with all clients.

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* In this report, unless otherwise mentioned the term provinces and provincial include territories and territorial respectively.

As a result of the small number of respondents in each category, meaningful numerical indicators such as percentages or statistics could not be computed. However, it was not the number of responses but the types of responses which were important indicators for the evaluation.

Dr. R. Nair, Professor, Professor of Epidemiology, University of Ottawa developed, under contract, the "generic" model of the disease surveillance and control system based on the conceptual framework developed by the evaluation team. The firm of Roy A. Anderson & Associates was hired to conduct consultations with clients and stakeholders, conduct document review and address 12 evaluation questions (see Appendix C for the executive summary of Roy A Anderson & Associates' report). Dr. Roy West, Professor of

Microbiology and Epidemiology, Memorial University provided a critical review of the evaluation report and recommendations.

The Laboratory Centre for Disease Control

The Laboratory Centre for Disease Control is one of five Directorates of the Health Protection Branch. LCDC has evolved from the Bureau of Hygiene, which was established in 1919. Today, LCDC has the following organizational units: 1) the Bureau of Communicable Disease Epidemiology, 2) the Bureau of Chronic Disease Epidemiology, 3) the Bureau of Microbiology, 4) the Bureau of Human Immunodeficiency Virus (HIV) and Human T-cell Lymphotropic Viruses (HTLV) Laboratories and Research, 5) the Office of Biosafety, 6) the Office of Biometrics, 7) the Risk Management/Strategic Planning, and 8) Administration.

LCDC has four advisory committees; namely, the Technical Advisory Committee (TAC), the Advisory Committee on Epidemiology (ACE), the National Advisory Committee on Immunization (NACI), and the Committee to Advise on Tropical Medicine and Travel (CATMAT). TAC and ACE is composed of provincial public health officials , who are direct clients and partners of LCDC in laboratory and epidemiology respectively. NACI and CATMAT is composed of recognized experts in their field and representatives of other committees as appropriate. These committees advise the Minister, and the Department on various aspects of disease surveillance and control activities. LCDC provides secretarial support to the committees.

LCDC is very active on the international scene. Its Bureau of Microbiology is recognized as an international centre of excellence in such areas as enteric pathogens and tuberculosis. The Bureau also provides laboratory services to the international community through programs organized by the World Health Organization (WHO) and Pan American Health Organization (PAHO).

LCDC's Office of Biosafety is a WHO Collaborating Centre in Biosafety Consultive Services. LCDC provides training courses to the international community.

LCDC's budget has increased from $8.98 million in 1983-84 to $24.44 in 1992-93. It had a compliment of 227 person-years in 1992-93.

Models of Disease Surveillance and Control Systems

At the time of the establishment of the Bureau of Hygiene (the predecessor of LCDC) in 1919, the disease surveillance and control activities generally focused on prevention, containment and control of epidemics which usually involved communicable diseases. Disease surveillance and control generally followed a medical and public health model. With the reduction of mortality and morbidity from communicable diseases, and more effective prevention of epidemics, the focus of the disease surveillance and control has shifted to the prevention, treatment and control of non-communicable diseases. Reduction of health risks through regulation, health promotion and education, and adopting health improving behaviours have become increasingly important. The role of non-health agencies in reducing harm to health have also become increasingly recognized.

Figure 1 on page 18 shows a conceptual framework of an ideal disease surveillance and control system which deals with both communicable and non-communicable diseases and with prevention and disease management strategies. The framework has four broad components; namely, research, surveillance, risk reduction, and treatment and management of diseases.

The Research component includes: research on methods for a) the identification, prevention, treatment, education and control of diseases and/or risk factors; b) risk assessment methods as they relate to disease surveillance and control; c) risk factors and diseases themselves; and the evaluation of health effects of regulations and programs;

The Surveillance component includes the monitoring of risk factors (e.g., ultra-violet rays, environmental contaminants, etc.), incidence of diseases (e.g., meningococcal disease, tuberculosis, birth defects, accidents, cancer, arthritis, etc.) and their outcomes. The surveillance also includes epidemiological investigations, and the collection, and analysis and dissemination on risk factors and disease. Surveillance does not include any actions taken either to reduce or to manage risk factors or diseases. The Surveillance component also includes the evaluation of health effects of regulations and programs, particularly of those regulations and programs which are designed to reduce health risks and/or to improve health;

The Risk reduction component includes health promotion, education, regulation (of industry, individuals and communities), and healthy public policy. Risk reduction also includes actions (e.g., stopping smoking, dieting, exercising) taken by individuals to avoid health risks. Preventive measures like vaccination, closure of beaches due to contaminated water, etc. also come under risk reduction; and

Treatment and management of disease (ill-health) component include actions taken after an individual has the disease. Laboratory and other testing are included in this component.

Figure 2 on page 23 shows the Canadian disease surveillance and control model which is consistent with the conceptual framework.

Major Findings and Conclusions

Role and mandate of LCDC

All the essential elements of the conceptual framework are present in the Canadian disease surveillance and control system. However, the system is highly decentralized and includes many organizations. It is essential that there exist a federal coordinating mechanism to avoid duplication of research and surveillance and to ensure a smooth ongoing flow of information. Such a federal agency could provide national and international intelligence, bring harmony to federal, provincial, community and local programs by providing uniform methods, models and information for decision making, maintain a national state-of-art microbiology laboratory capability for diagnostic services, and provide support and advice to the public health system.

In particular, the ideal role of LCDC could include:

- the development of the methods, tools and protocols for disease and risk factor surveillance, risk assessment, and risk management,
- the conduct of national level disease surveillance and international intelligence, and the conduct of special epidemiological and risk assessment studies,
- the promotion of and support to the evaluation/monitoring of the effects of federal regulations and programs on the health of Canadians,
- the development, analysis and provision of information and advice required for the efficient functioning of the Canadian disease surveillance and control system,
- the administration of the quarantine program, and
- the provision of laboratory and epidemiological support to provincial, territorial, community and regional public health agencies as well as other health care givers in their efforts of disease management.

The clients and stakeholders confirmed the need for an agency like LCDC and its ideal role. They feel that LCDC has mandate to satisfy its obligations.

LCDC is currently active in all the four broad components of the Canadian disease surveillance and control system. However, it does not have a formal mandate to evaluate the effects of federal regulations and programs on the health of Canadians.

LCDC should ideally have the mandate to collect and maintain risk factor - health effects information and conduct such evaluations. However, it would not be practical for LCDC to evaluate the health effects of every federal regulation and program. In any event, regulating agencies and program managers would have to monitor effects (including health effects) of their programs and make changes to regulations and programs as necessary. LCDC could develop methods for, promote and participate in the evaluation of health effects.

Gaps and overlaps

There are no major gaps and overlaps within the Canadian disease surveillance and control system, with the exception of a lack of responsibility for evaluating the health effects of regulations and programs. Clients and stakeholders have identified a number minor gaps or duplications. However, these gaps and duplications are not serious. Clients want more of the services and products they receive from LCDC.

The disease surveillance and control field is very large. Any agency like LCDC, regardless of the resources available to it, would not be able to maintain surveillance on all diseases, develop and maintain expertise on methods of their control, and stay at the frontier of technology and

knowledge. LCDC may have to carefully select in-house projects and to reallocate resources to carry out its challenging role successfully and to meet the changing client needs and expectations.

Risk assessment

LCDC has many risk assessment projects underway. Its role and program are relatively unknown to its external clients. LCDC's clients feel that LCDC has a legitimate role in risk assessment but that risk management is a provincial responsibility. LCDC can contribute to risk reduction/management within the Canadian disease control system by developing methods, models and information for risk assessment and transferring this knowledge and information to those who are involved in the risk assessment/management.

Client expectations and satisfaction

Most LCDC's clients receive some product or service they do not or can not get from other sources. They feel that many LCDC services and products are essential for them in carrying out their responsibilities.

The clients of LCDC are generally satisfied with the services and products they receive from LCDC. However, a majority of them complained about the delays in obtaining LCDC services and products, lack of sufficient backup expertise at LCDC during emergencies and staff turnover, and poor communication between LCDC and them. Notwithstanding the complaints, the clients mentioned that they have noted significant changes at LCDC and for better. They felt that LCDC has now become more client oriented than before.

Provincial public health officials expressed great satisfaction with the field epidemiology and the laboratory biosafety training program, and specialized workshops and courses in laboratory methodology.

The field epidemiology training program has expanded from about three trainees, when it started, to ten presently. However, many small provinces, who have greater need for such support, do not have continuing access to these trainees. They felt that the current epidemiology training program need to be expanded so that all provinces have equal access to the trainees.

Clients of LCDC do not see it as a source for world literature. Most of them have sufficient access to computerized sources of information. They, however, consider LCDC to be a valuable source for national and international disease surveillance information.

Technology transfer

The primary objective of LCDC is to support the disease surveillance and control system and not to conduct research for the sake of research. However, during the course of its work, LCDC has to develop new or to significantly modify existing technologies and processes to fulfil its own needs. These technologies and processes include, laboratory methods, epidemiological and analytical methods, computer software, etc. These, if transferred to its clients and stakeholders, would benefit the Canadian disease surveillance and control system as a whole and, thus, produce public good. And, there are examples of successful transfers of both commercially exploitable and non-exploitable technologies within LCDC.

While some of these technologies can be commercially exploited and are suitable for transferring to industrial sector, many innovations are not commercially profitable. Further, LCDC may be able to publicize its own innovations through its own national and international network. However, it does not have the mandate, resources and infrastructure of its own to market its innovations itself.

The recent memorandum of agreement between the Health Protection Branch and the Intellectual Property Service Office of the National Research Council will provide a mechanism for transferring commercially exploitable technologies to the private sector. However, there are no formal internal mechanisms within LCDC for identifying transferrable technologies, promoting the transfer and monitoring the transferred technologies.

Cost recovery

The last evaluation recommended that LCDC should recover the costs those of its services and products which are not deemed to be essential. These would include its publications, reagents, etc.

LCDC has four routine, five occasional and several specific issue related publications. It only recovers the costs of the Canadian Communicable Diseases Report, a biweekly publication. As a result of the cost recovery, the circulation of this publication has decreased from about 11,800 to 2,500. This decrease has reduced LCDC's ability to reach some of its indirect clients. LCDC now provides free access to this publication through its FAXLINK service. While this free access is contrary to the cost-recovery, it allows LCDC to reach more of its constituents.

Since the last evaluation, LCDC has eliminated a unit dedicated for the production of reagents. However, it still provides reagents which are either commercially not available or commercially available but not suitable for public health laboratory use. These reagents are deemed to be essential by its stakeholders.

A Departmental study which looked at HPB services and products for cost-recovery, concluded that LCDC's services and products should not be considered for cost-recovery. Stakeholders feel that LCDC's services and products are essential to the Canadian public health and health care system. Further, that many products and LCDC expertise are developed from information and samples provided by them. If LCDC institutes a charge for its services, they may have to begin charging for the information and samples they provide, and/or consider establishing their own capabilities. In this scenario, LCDC's expertise and central place in the Canadian disease surveillance control system would erode over time.

LCDC laboratories

LCDC has six in-house specialized National Laboratories which provide state-of-the-art diagnostic and investigative laboratory services related to specific pathogens to the provincial public health laboratories. In addition, LCDC has contracted nine provincial laboratories (called National Centres) to provide similar services for other specific pathogens. The National Laboratories and National Centres also provide proficiency testing program for other public health laboratories across Canada, and specialized training courses in their field of expertise.

These arrangements improve the efficiency of the Canadian public health laboratory system by efficiently using the scarce scientific resources, making high quality experienced services available to all provinces, and avoiding the need to duplicate expertise. However, there are some disadvantages because the resources of the National Centres vary from Centre to Centre, and so do their efforts in research and in keeping at the forefront of technology. There is also the possibility that the host organization which houses a National Centre may, on its own, decide to discontinue its services.

Overall, the National Laboratories and National Centres together are working well and to the satisfaction of the provincial public health laboratories. However, the turnaround time for obtaining results of the tests conducted by the National Laboratories - they are all housed in Ottawa - is often too long and not useful in primary patient care.

Mechanisms for Keeping Laboratories Current

National Laboratories and National Centres try to keep current through a number of mechanisms; for example, through encouraging their staff to participating in training programs, conferences, workshops, and peer reviews, through cross appointments with universities, and through conducting research, etc. Most of the scientific professionals keep current because of a feeling of professional obligation and to maintain recognition among their peers.

Some of the contracts with National Centres do not explicitly mention the requirements for keeping current and for training. Also, some National Centres are paid a nominal sum. These Centres see their budgets strained.

Alternative organizational arrangements

Currently, LCDC is a Directorate of the Health Protection Branch. LCDC has been able to fulfil its mandate and obligations to the satisfaction of its clients. The evaluation examined if any alternative organizational arrangement for LCDC would increase its contribution to the Canadian disease surveillance and control system. The following six alternatives were considered: 1) status quo, 2) LCDC reports directly to the Deputy Minister of HWC, 3) LCDC reports directly to the Minister of HWC, and 4) LCDC becomes a special operating agency (SOA), 5) LCDC becomes a communicable disease institute, and chronic disease epidemiology moved closer to health promotion, or merged with the proposed Canadian Institute for Health Information and 6) LCDC becomes an independent agency funded by federal and provincial governments and other sources.

In determining if any of these alternatives are worth pursuing further, the evaluation assumed that LCDC would continue to

a) provide current services and products to its partners and stakeholders;
b) provide advice to the Minister of Health and Welfare Canada on matters related to disease surveillance and control;
c) be able to respond to emergencies, outbreaks at the national level and new diseases;

d) retain its leadership role across the country in the areas of disease surveillance and control; and

e) that any alternative arrangements would not compromise the ability of the federal government and HWC to ask LCDC to address important issues of national health concern on an urgent basis.

The evaluation also compared the organizational setting of the US Centers for Disease Control (CDC) in Atlanta within the US federal bureaucracy with that of LCDC within the Canadian federal bureaucracy. CDC's mandate, role and programs and the client structure is similar to that of LCDC. CDC is considered to be a very successful agency at the forefront of disease surveillance and control. Hence, the comparison provided useful information for the evaluation.

CDC is independent of regulating agencies within the US system, on the other hand, LCDC is a part of a Branch with regulation as its principal instrument for health protection. CDC's programs include health promotion. This ensures that CDC's work is integrated in health promotion. Within Health and Welfare Canada, LCDC and Health Promotion Directorate are parts of different Branches with no formal mechanisms in place to ensure that LCDC's work is systematically used in health promotion.

LCDC's main clients are involved in public health, health care, surveillance, health promotion and education. On the other hand, main clients of other Directorates within the HPB are industry and other provincial industry regulators. LCDC's focus is on Canadians while other HPB branches focus on materials and processes they regulate. As mentioned before, LCDC lacks the independence for formally conducting retrospective evaluations of federal regulations on the health of Canadians.

While 60% of external clients consulted were satisfied with LCDC's current organizational placement within Health and Welfare Canada, the remaining 40% felt that LCDC's potential for contribution could be enhanced if it was not a part of the Health Protection Branch.

Except the status quo and the alternative where LCDC reports directly to the Deputy Minister, all other alternatives were determined to be not worth pursuing further.

While, the benefits of LCDC reporting directly to the Minster over its reporting to the Deputy Minister were judged to be marginal, the risk of LCDC becoming ineffective are significant.

While, LCDC could function as a special operating agency (SOA), it would have difficulty in recovering the costs of its operation from its clients. Also, there is a potential of LCDC loosing, over time, its expertise and central place in the Canadian disease surveillance and control system, if it were to become a special operating agency. Because of the current government expectation that a SOA should recover full costs of its operation, this alternative is considered not worth pursuing.

The alternative of LCDC becoming a communicable disease institute does not address the issue of the location of LCDC. Also, removing the Bureau of Chronic Disease Epidemiology out of LCDC does not make sense if its programs go beyond information collection and dissemination, and if it requires the participation of field epidemiologists. However, strengthening the ties between the Bureau and Health Promotion Directorate would enhance the usefulness of the results of Bureau's work.

The alternative where LCDC becomes an independent agency does not satisfy all the assumptions and hence considered not worth pursuing.

While the status quo is satisfactory, there is a potential for increasing LCDC's effectiveness and its contribution to the Canadian disease surveillance and control system, if LCDC were to report directly to the Deputy Minister.

credits

Madhu Joshi of the Program Evaluation Division was the Project Leader.

Silvia Olivares-Guevara of the Program Evaluation Division was a member of the evaluation team.

Guenter Riedel, Ph.D. of the Field Operations Directorate, Health Protection Branch was seconded to the Program Evaluation Division for the evaluation study.

Carmen Labre of Program Evaluation Division provided support to the Project.

R. Nair, Ph.D. of University of Ottawa developed a generic model for Disease Surveillance and Control System

Roy A. Anderson & Associates Conducted client consultations, document reviews and answered twelve evaluation questions.

Roy West, Ph.D. of the Memorial University, St. John's, Newfoundland conducted a critical review of analysis, findings and recommendations.

chapter one

introduction

This report presents the findings and conclusions of the evaluation of the Laboratory Centre for Disease Control (LCDC) of the Health Protection Branch. The evaluation covered all activities of the Laboratory Centre for Disease Control - with the exception of the activities related to the surveillance and control of AIDS. This report refers to the Laboratory Centre for Disease Control as LCDC, the Program or the Centre.

Part III of the Main Estimates describes LCDC as the "National Health Surveillance Program." This description implies that the Program is only concerned with monitoring (surveillance) of diseases. On the other hand, the current name "Laboratory Centre for Disease Control" implies that LCDC is involved only in disease control activities. However, in actuality, the Program is concerned with all aspects of the identification, surveillance and control of diseases, and the identification and surveillance of risk factors.

The planning for the evaluation began in October 1991, and the evaluation began in May 1992. The field work was completed by October 1992. The evaluation required 20 person months and $65,300, of which $60,250 was for contracts.

The Laboratory Centre for Disease Control

The Laboratory Centre for Disease Control has its origins in the Bureau of Hygiene which was established in 1919 under the Health and Welfare Act. Today LCDC has the identification, investigation, control and prevention of the human disease as its objectives and mission. In 1992-93, the resources of LCDC included 227 PYs and $24.4 million (including salary costs). Of these resources, 37 PYs and $4.97 million were for AIDS related activities. A more detailed description of the organization and activities of LCDC is found in Chapter 2 (Program Description) of the report.

Internal and External Reviews of LCDC

This is the second formal program evaluation of LCDC. The Program was last evaluated in 1984-85. That evaluation made a total of 21 recommendations (see appendix E) encompassing the mandate and activities of LCDC. In addition to the 1984-85 evaluation, LCDC had also commissioned a number of external reviews of its activities. These included:

1. External Review, Cancer Section, Bureau of Chronic Diseases, Laboratory Centre for Disease Control, F. White (Chairman, Review Committee), (April 1991).

2. A Strategic Plan for the Bureau of Chronic Disease Epidemiology, Laboratory Centre for Disease Control, Communication Management Consultants, Pakenham, Ontario, K0A 2X0. (March 1991).

3. Review of the National Laboratory for STDs at LCDC performed by R.C. Brunham, (November 1990).

4. External Evaluation of the National Laboratory for Sexually Transmitted Diseases, Laboratory Centre for Disease Control, Ottawa, Ontario prepared by W.L. Albritton, University of Alberta, Edmonton, Alberta, (April 1991).

5. Communication Strategy: Consultation with Public Health Professionals, Dr. Neima Langner, (August 1992).

The evaluation used the findings and conclusions of these reviews as background documents.

Scope and Objectives of the Evaluation

During the planning stage of the evaluation, LCDC was not responsible for AIDS related epidemiology and laboratory activities, the Federal Centre for Aids was.* Therefore, this evaluation does not include AIDS related issues and questions.

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* In 1992, the Federal Centre for AIDS was reorganized, a separate National AIDS Secretariat reporting to the Associate Deputy Minister was created to coordinate Departmental activities related to AIDS and the responsibility for AIDS related epidemiology and laboratory work was transferred to LCDC.

The Planning Phase of the evaluation study identified the following seven general issues for the evaluation:

1. The role of LCDC,
2. Risk assessment,
3. The relevance and the quality of expertise and services provided to clients and partners, and the level of expertise developed and maintained by LCDC,
4. The extent to which LCDC fulfils the expectations of its clients and partners,
5. Technology transfer,
6. Cost-recovery, and
7. Alternative organizational arrangements.

The evaluation examines 18 questions (see appendix A) to address the seven general issues. To the extent possible, this evaluation has avoided duplication with the last evaluation.

Evaluation Methods and Information

The evaluation uses a systems analysis approach and qualitative methods.

The system analysis approach is used in examining the role and mandate of LCDC. This involved developing a conceptual framework, a "generic" model and a model of the Canadian disease surveillance and control system, and examining the current functions and activities within the context of these models. Dr. R. Nair, Professor of Epidemiology, University of Ottawa developed the "generic" model of the disease surveillance and control system based on the conceptual framework developed by the evaluation team. (A brief summary of Dr. Nair report is included in Appendix B).

LCDC's work covers a large area of the disease surveillance and control system. However, apart from the administration of the Quarantine Act, LCDC has no direct health care delivery program of its own. It influences the health care in Canada through provincial health care systems. Therefore, it is not possible to directly measure (or estimate) the contribution of specific LCDC initiatives to the improvement of the health status of Canadians. However, it is possible to evaluate the Program using inductive and/or qualitative methods.

The evaluation conducted five case studies which examined the role of LCDC and the impact of its activities on the disease surveillance and control system. These case studies provide illustrations of the effectiveness of LCDC. The case studies included: 1) Domoic Acid Food Poisoning, 2) Food-Borne Infections, 3) Office of Bio-Safety, 4) Canadian Hospital Injury Reporting and Prevention Program, and 5)

Tuberculosis. The results of these studies are summarized in Appendix D and are used throughout the evaluation.

The evaluation is based on program and other documents and published literature, and consultations with clients and partners of LCDC as well as program officials. Consultations were also held with officials of US Centers for Disease Control in Atlanta.

The clients and partners of the Program included members of various LCDC committees, provincial epidemiologists, heads of provincial public health laboratories, TB control directors, and representatives of selected voluntary organizations, officials of Health and Welfare Canada (outside the Program), and researchers in the health field. None of these categories of clients had more than a dozen individuals.

A total of over 140 persons were consulted for the evaluation. These included about 85 clients and stakeholders outside Health and Welfare Canada, over 20 Program officials, 20 persons from HWC but outside the Program, and about 15 from CDC.

A master protocol was designed for consultations. It was understood that not all questions were applicable to all types of clients. For example, questions related to the running of laboratories were only applicable to the members of the Technical Advisory Committee and laboratory personnel. However, some questions such as, client expectations, what role should LCDC play, etc. were discussed with all clients. As a result of the small number of respondents in each category, meaningful numerical indicators such as percentages or statistics could not be computed. However, it was not the number of responses but the types of responses which were important indicators for the evaluation.

The firm of Roy A. Anderson & Associates was hired to conduct consultations with clients and stakeholders, conduct document review and address 12 evaluation questions (see Appendix C for the executive summary of Roy A Anderson & Associates' report). Six evaluation questions related to cost recovery and technology transfer issues were addressed by the evaluation team. Dr. Roy West, Professor of Microbiology and Epidemiology, Memorial University provided a critical review of the evaluation report and recommendations.

chapter two

LCDC program description and organization

The Laboratory Centre for Disease Control

The Laboratory Centre for Disease Control is one of five Directorates of the Health Protection Branch. Since its inception in 1919 under the Health and Welfare Act as the Bureau of Hygiene, LCDC has been the subject of several reorganizations:

- in 1921, it was renamed the Laboratory of Hygiene;
- in 1947, the Laboratory of Hygiene underwent fundamental restructuring by Order in Council which created the Technical Advisory Committee (TAC) on Public Health Laboratory services and established a separate Division of Epidemiology;
- in 1950, a Bureau of Medical Biochemistry was added;
- in 1962, an Advisory Committee on Epidemiology (ACE) was established;
- in 1972, the Laboratory of Hygiene and the Division of Epidemiology united to become what would be the Laboratory Centre for Disease Control; and
- more recently, mainly in response to recommendations of the 1984-85 evaluation study, a number of changes were made. These included a) the elimination of the Bureau of Medical Biochemistry, Infection Control, and Tobacco and Biometrics, b) the creation of the Division of Biosafety, c) the creation of the Bureau of Chronic Disease Epidemiology and the Bureau of Communicable Disease Epidemiology out of the Bureau of Epidemiology, and d) the establishment of the Risk Management/Strategic Planning Unit.

The total budget of LCDC has increased from $8.98 million in 1983-84 to $24.44 Million in 1992-93. In 1992-93, LCDC's budget included $7.20 million for work related to special initiatives, while in 1983-84, there were no projects funded through special initiatives.

The field epidemiology training program, offered by LCDC, has also expanded. In 1975, when the training program began it had four trainees. In 1992-93, it had ten trainees. Since its inception, a total of 49 trainees have undergone the training. With the increase in the number of trainees, LCDC has been able to provide more support to the provinces and to undertake more field epidemiology investigations

Mandate

Today LCDC monitors, investigates and manages risks to the health of Canadians. The Centre directly supports the Branch's mandate of protecting the Canadian public from health risks posed by microbial, foodborne, drug related and environmental hazards. Through its laboratory, national health surveillance, and disease investigation activities; LCDC plays a vital role in health risk management.

Mission

LCDC's mission is to be *the national centre for the identification, investigation, control and prevention of human disease.*

Organizational Structure

LCDC's organizational structure includes:

- the Bureau of Communicable Disease Epidemiology,
- the Bureau of Chronic Disease Epidemiology,
- the Bureau of Microbiology,
- the Bureau Human Immunodeficiency Virus (HIV) and Human T-cell Lymphotropic Viruses (HTLV) Laboratories and Research,
- the Office of Biosafety,
- the Office of Biometrics,
- the Risk Management/Strategic Planning, and
- Administration.
- Four Advisory Committees

An outline of the activities of each of these units follows.

The Bureau of Communicable Disease Epidemiology conducts national surveillance, special studies on infectious diseases and outbreak investigations. It develops and/or coordinates the development of guidelines for disease control programs. The Bureau provides advice and support to the provincial health departments in surveillance and control of communicable diseases. It also provides field epidemiology training courses. The Bureau's main areas of activity are nationally notifiable communicable diseases, sexually transmitted diseases, childhood and adult vaccine-preventable diseases, hepatitis as special pathogens, tropical health and quarantine, and HIV/AIDS.

The Bureau of Chronic Disease Epidemiology monitors and analyses Canada's vital and health statistics, and publishes reports on patterns of disease, hospitalization, injury and death. It organizes and promotes national workshops, conferences and studies on emerging problem areas, for example, on age-related diseases such as Alzheimer's and other dementias, and osteoporosis. The Bureau conducts research on the occurrence and causes of injuries and major chronic diseases and on chronic disease prevention and control. The Bureau's main areas of

activity include: Cancer, Childhood diseases (including low birthweight, birth defects and asthma), injuries to children, and aging-related and other chronic diseases.

The Bureau of Microbiology The Bureau has established a network of fifteen laboratories which provide diagnostic and investigative laboratory services related to infectious diseases to provincial public health laboratories and (on occasion) to tertiary care hospitals. The network includes six in-house laboratories in Ottawa (designated as National Laboratories) and nine provincial or university laboratories under contract (called National Centres). Through its international programs which are organized through the World Health Organization (WHO) and the Pan American Health organization (PAHO), the Bureau provides laboratory services to the international community. It is designated as an international centre of excellence in such areas as enteric pathogens and tuberculosis.

The Bureau activities consist of: a) state-of-the-art laboratory services related to the detection of established and emerging diseases, and to uncommon or analytically challenging specimens; b) development and production of diagnostic reagents and standards not commercially available; c) specialized epidemiological services in the event of specific disease outbreaks; and d) investigative services for the assessment, improvement and standardization of laboratory diagnostic and safety procedures used in hospitals and laboratories. The Bureau also provides laboratory training courses.

The Bureau of HIV and HTLV Laboratories and Research provides Canadian public health and research laboratories with a national diagnostic and expert reference services for HIV and HTLV I and II. The Bureau provides expertise in two main areas: the detection of HIV infection and the measurement of changes in the immune system related to HIV infection. Research is carried out on the pathogenesis and pathophysiology of HIV, development of new diagnostic and expert viral reference services, population studies, assessment of antiviral agents, and viral drug resistance and HIV vaccine assessment.

As noted in chapter one, the activities of the Bureau of HIV and HTLV are not covered in the evaluation.

The Office of Biosafety provides national advisory services on safety in microbiology laboratories and data on laboratory-acquired infections and accidents. It also provides guidelines and advice, nationally and internationally, on all aspects of biosafety. The Office is a WHO Collaborating Centre in Biosafety Consultive Services.

The Office also administers the "Laboratory Safety Guidelines," which are jointly published by Health and Welfare Canada and the Medical Research Council. These guidelines set out national biosafety practices and containment requirements applicable to research institutions and to diagnostic, teaching and public health laboratories.

The Division of Biometrics provides internal support in LCDC computer services and provides biostatistical expertise. The computer services include the provision of operational support, management of contracts, systems analysis, computer system design, and implementation of a wide range of Centre's applications. Division's biostatisticians are involved in a wide spectrum of activities include sample design for field and laboratory studies, data analysis and modelling of epidemics, and the development of analytical methods for evaluating disease-related information.

The Risk Management/Strategic planning Unit supports LCDC's role in the identification, assessment and management of health risks to the Canadian public. It works with the bureaux to develop risk management strategies and to provide policy and program branches with relevant surveillance and risk assessment data.

Administration supports the Office of the Director General in managing the Centre.

Advisory Committees: In addition to its internal operational units, LCDC has four advisory committees. These committees advise the Minister, and the Department on various aspects of disease surveillance and control activities. LCDC provides secretarial support to the committees.

The Technical Advisory Committee (TAC) was created in 1947 by Order in Council to assist and advise the Minister of HWC on matters relating to public health laboratory service in Canada. The role of the TAC is to facilitate cooperation between LCDC and Provincial laboratories, coordination of efforts and activities, and exchange of technical information. The TAC is composed of the provincial public health laboratory directors.

The Advisory Committee on Epidemiology (ACE) was established in 1962 by Order in Council to assist and advise the Minister and appropriate officers of Health and Welfare Canada (HWC) on matters relating to the study, prevention and control of communicable and non-communicable diseases. It is composed of the provincial and territorial epidemiologists.

The National Advisory Committee on Immunization (NACI) was established in 1964 to advise the Assistant Deputy Minister, HPB on the use of currently or newly licensed vaccines for human use in Canada, and on the development of national vaccination strategies. The NACI also makes recommendations concerning vaccine development research. Its members include recognized experts in paediatrics, infectious diseases, immunology, medical microbiology, internal medicine, federal public servants, and ACE liaison members.

The Committee to Advise on Tropical Medicine and Travel (CATMAT) was formed in 1990 on the advice of the ACE, to make recommendations to the Assistant Deputy Minister of the Health

Protection Branch (HPB) on the prevention and treatment of tropical infectious diseases and other potential health hazards faced by Canadian travellers abroad. Its members include recognized travel tropical medicine experts, federal public servants and liaison members of other committees (ACE, NACI).

Resources

LCDC's organization and distribution of resources for fiscal year 1992/93 is described in the Table below:

Bureau/Unit	Capital Budget ($)	Salary Allocation ($)	Operating Budget ($)	TOTAL Budget ($)	PYs Allo.
Communicable Disease	110,000	2,099,647	1,196,697	3,406,344	41
Chronic Disease	576,166	2,155,034	3,940,133	6,671,333	37
Microbiology	367,000	4,098,859	2,160,773	6,626,632	92
Director General's Office	129,300	1,220,360	1,413,237	2,762,897	20
AIDS		1,840,550	3,129,200	4,969,750	37
TOTAL	1,182466	11,414,450	11,840,040	24,436,956	227

Source: LCDC

Clients

LCDC's direct clients, partners and stakeholders include:

Provincial, Regional and Local public health departments. Provincial Ministries of Health are the principle direct clients and partners of LCDC. Through them, LCDC also serves regional and local public health departments.

Federal. Through its surveillance, laboratory programs and data analysis activities, LCDC supports various federal government, programs (e.g., Food Safety, Quality and Nutrition Program).

Health Care professionals. LCDC publications, presentations and seminar activities provide current Canadian public health information to researchers and health care professionals. It also provides training in the field of epidemiology and microbiology.

NGOs. These include professional associations such as the Canadian Public Health Association, Canadian Paediatric Society, universities and teaching hospitals, and voluntary agencies such as Canadian Cancer Society.

International Agencies. LCDC liaises with World Health Organization (WHO), Pan American Health Organization (PAHO), the United States' Centers for Disease Control (CDC), and many other international agencies to exchange information, and to provide laboratory and training services.

chapter three

findings and conclusions: LCDC mandate and role

This chapter presents the findings and conclusions of the following nine evaluation questions dealing with the mandate and role of LCDC, and client expectations:

1. What is an ideal role for LCDC, given the current provincial and federal mandates in disease surveillance and control?

2. What role should LCDC play in the development of risk assessment and management for the disease surveillance and control system?

3. How consistent is LCDC's current role with the "ideal' role?

4. What gaps exist in the system?

5. What modifications to LCDC's role are necessary to eliminate gaps and unnecessary overlaps in Canada's disease surveillance/control system?

6. What are the expectations of clients and partners (stakeholders)?

7. How consistent are the expectations with the LCDC's current and ideal roles?

8. What types of resources are necessary for LCDC to fulfil these expectations?

9. How and to what extent does LCDC fulfil it's mandate and the expectations of its clients/stakeholders?

The last evaluation of LCDC had addressed the mandate of LCDC and the need for its services. It concluded that, with a few exceptions, all the persons interviewed at that time were "unanimous as to the need for a national centre such as LCDC". It also concluded that LCDC's role in providing "back-up and assistance in public health laboratory and epidemiological systems remains a valid task for the federal government to undertake". Further, the evaluation found that the activities carried out by LCDC were consistent with the mandate of the Department. Nothing much has changed with respect to these points since the last evaluation.

Evaluation Approach

This evaluation examines LCDC's role in a more general framework of disease surveillance and control, client expectations and their fulfilments from the client perspectives. The evaluation also examines LCDC's efforts in risk assessment.

A conceptual framework and a "generic" model for a disease surveillance and control system were developed to identify various components of the system and their interrelationships. A corresponding model for the Canadian system was also developed. The framework and the models were used to examine the role of LCDC and to identify any significant gaps and overlaps in the Canadian system.

All those who were consulted, were asked their opinion about what role should LCDC play in disease surveillance and control and in risk assessment; their expectations from LCDC and the extent to which the expectations are fulfilled; and what gaps and overlaps existed in the system. The information from consultations was also used for the examination of the nine questions.

A Conceptual Framework for the Disease Surveillance and Control System

At the time of the establishment of the Bureau of Hygiene (the predecessor of LCDC) in 1919, the disease surveillance and control activities generally focused on prevention, containment and control of epidemics which usually involved communicable diseases.

With the reduction of mortality and morbidity from communicable diseases, and more effective prevention of epidemics, the focus of the disease surveillance and control has shifted to the prevention, treatment and control of non-communicable diseases. This does not mean that the disease surveillance and control systems do no longer deal with communicable diseases. To the contrary, newer infectious diseases are being identified (e.g., legionnaire's diseases, AIDS, etc.) and older diseases are coming back with newer and/or drug resistant strains (e.g., malaria, tuberculosis) requiring considerable resources from the health systems.

Figure 1 (see fold-out facing this page) shows a conceptual framework for a disease surveillance and control system which deals with both communicable and non-communicable diseases. The framework attempts to identify and integrate various essential functions of health care and other sectors which contribute to the surveillance and control of diseases.

The framework consists of four broad components representing four different types of functions. It would be equally possible to reorganize the framework by responsibilities rather than by functions. The representation of the framework by functions permits a more logical discussion of the role of LCDC (and other stakeholders in the system), and hence is used here. The four functions are

1. **Research** on methods for a) the identification, prevention, treatment, education and control of diseases and/or risk factors; b) risk analysis, cost-benefit-effectiveness analysis and feasibility analysis methods as they relate to disease surveillance

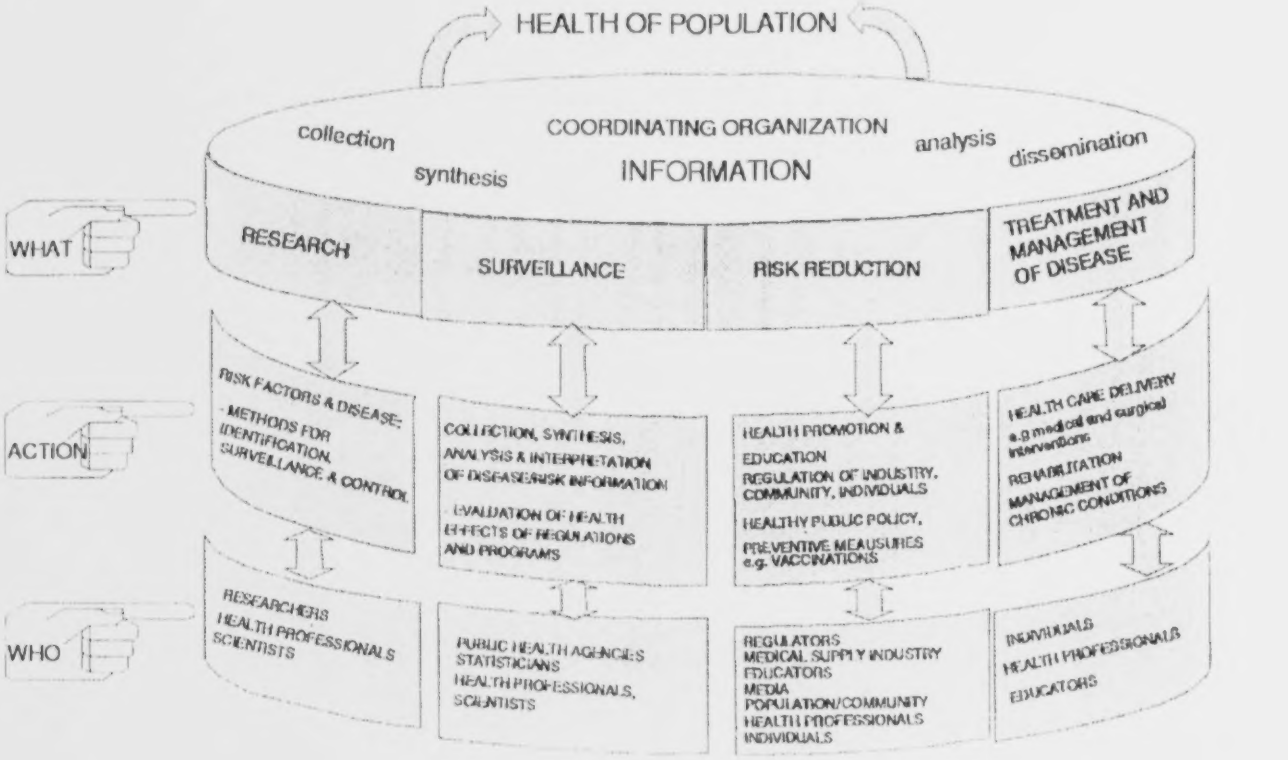
and control; c) risk factors and diseases themselves; and d) the evaluation of health effects of regulations and programs;

2. **Surveillance** or monitoring of risk factors (e.g., ultra-violet rays, environmental contaminants, etc.), incidence of diseases (e.g., meningococcal disease, tuberculosis, birth defects, accidents, cancer, arthritis, etc.) and their outcomes. For the purpose of this discussion, surveillance includes epidemiological investigations, and the collection, synthesis, analysis and interpretation of information on the presence, incidence and occurrence of risk factors and disease entities. Surveillance does not include any actions taken either to reduce or to manage risk factors or diseases. The Surveillance component also includes retrospective evaluation of health effects of regulations and programs, and, in particular of those regulations and programs which are designed to reduce health risks and/or to improve health;

3. **Risk reduction** includes health promotion, education, regulation (of industry, individuals and communities), and healthy public policy. Risk reduction also includes actions (e.g., stopping smoking, dieting, exercising) taken by individuals to avoid health risks. Preventive measures like vaccination, closure of beaches due to contaminated water, etc. also come under risk reduction; and

4. **Treatment and management of disease (ill-health)** through health care delivery. These include actions taken after an individual has the disease. Laboratory and other testing are included in the treatment and management component.

FIGURE 1. DISEASE SURVEILLANCE AND CONTROL SYSTEM - CONCEPTUAL FRAMEWORK



Collection, synthesis, analysis and dissemination of information are integral parts of all four components and are not shown separately.

The **Research** component represents "knowledge and information" about risk factors and diseases, their effects and interrelationships, and methods for their identification and control. The **Surveillance** component provides intelligence on the presence and potential for risk factors and disease entities. The **Risk reduction** component includes prevention and control of risk factors and diseases through promotion, education, regulation and pursuit of public policies which maintain or improve health. The **Treatment and management of ill-health** component mainly concentrates when disease occurs.

For the purpose of this report, risk assessment falls in **Research** while risk management is covered by **Risk reduction**. Risk assessment develops information on hazards and options for controlling them, risk factor surveillance measures the level of risk present, and risk management implies interventions to reduce or control risks.

Of the four components, the **Treatment and management of ill-health** involves predominantly, the public health and health care systems as well as individuals. The other three involve public health and health care systems, universities, industry, voluntary organizations, communities, regulators and other public sector agencies, media, as well as individuals.

A Generic Model of the Disease Surveillance and Control System

Dr. Rama C. Nair, Professor of Epidemiology, University of Ottawa has developed, for this evaluation, a "generic" model of the disease control and surveillance system" which reflects the changing nature of the system. The model is fully described in his report " System for Disease Control and Surveillance - A "generic" model. This report refers to the Nair model as the "generic" model.

The report recognizes that with the reduction in mortality and morbidity from communicable diseases, and the prominence of chronic diseases by any criteria of "burden of illness", the management of disease including treatment and rehabilitation has become a major component of any disease control activity in developed countries. Along with this shift has come increasing expectations from the public health systems to enhance their efforts for disease surveillance and control in non-communicable disease area.

The report observes that while the primary purpose of a national health system is the preservation of good health of its population, in most jurisdictions, they concentrate on "medical aspects" of health, and give relatively less importance to "public health" aspects and to the contribution of other sectors.

Many sectors outside the health system impact on the health of the population. Examples include, law enforcement agencies' efforts to combat and control family violence, transportation agencies' regulations

for the movement of dangerous goods, and agricultural sectors efforts to develop more nutritious foods are potentially beneficial to human health. The model incorporates the activities of such sectors and recognizes their role in the identification, surveillance, prevention and control of risk factors and ill-health.

An efficient information management system, i.e., the development of up-to-date, reliable and valid information and the free flow of information, is necessary for an effective disease surveillance and control system.

The conceptual framework and the "generic" model are universally and generally applicable to all geo-political entities (communities, provinces/states and nations) irrespective of their health care and risk reduction systems. All elements of the framework and the model need to be present and working well with each other for the disease surveillance and control system to be effective and efficient.

The next section presents a model of the current Canadian disease surveillance and control system. The presentation of the Canadian model is consistent with the conceptual framework and the "generic" model. The Canadian model is used for further exploring the role of LCDC within the context of the disease surveillance and control in Canada.

Canadian Disease Surveillance and Control System

In Canada, many different organizations, within both the public and private sectors, contribute to and are part of the disease surveillance and control system. Some organizations have specific health objectives as their primary function, while others contribute to the System as a by-product of their mission.

Examples of the former type organizations include: federal, provincial and community-based health agencies, hospitals, the medical profession, private sector public health laboratories, voluntary agencies dealing with health care and management, and university and industrial researchers. Law enforcement agencies (deal with traffic accidents, family violence, etc.), weather measurement and forecasting organizations (e.g., provides ultra-violate index), agriculture industry, the transport sector all contribute to the disease surveillance and control system indirectly and are examples of the latter types of organizations. The mandates, activities and effects, which relate to the disease surveillance and control system, of all such organizations should be taken into account for determining the ideal role for LCDC.

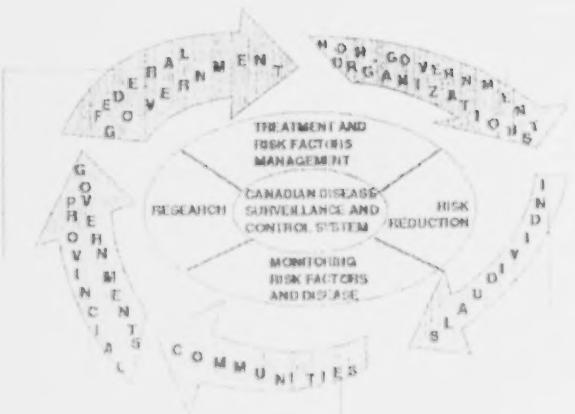
It would almost be impossible to chart all the numerous organizations and their activities and interrelationships in a single chart. A simplified version of the current Canadian disease surveillance and control system, which shows key players in the system from the LCDC perspective, is included in Figure 2 (see fold-out facing this page).

To facilitate the understanding of the role of LCDC within the context of the Canadian system, Figure 2 shows roles and functions of LCDC, federal regulators, and other federal agencies separately. At the provincial/territorial/community level, public health agencies, health

care delivery organizations and regulatory agencies are shown separately. The participation of individuals in adopting reduced-risk or risk-free behaviour and in seeking health care are essential for an effective system, and hence are shown separately. The non-government sector has three types of organizations: universities (research), industry (research, technology, products and services) and voluntary organizations (treatment and management of ill-health, information on ill-health and support of individuals and families) which contribute to the disease surveillance and control system.

The Canadian disease surveillance and control system has all the essential elements, with the exception of the responsibility for evaluating health effects of regulations and programs. However, the system is highly decentralized and includes many organizations. It is important that there exist a coordinating mechanism to avoid duplication of research and surveillance and to ensure a smooth ongoing flow of information.

FIGURE 2. DISEASE SURVEILLANCE AND CONTROL SYSTEM - CANADIAN MODEL



LABORATORY CENTRE FOR DISEASE CONTROL

- laboratory services
- epidemiology
- support to provincial public health surveillance
- quarantine
- guidelines on laboratory safety, immunization, etc.
- ensuring health information flow within the system

ADVISORY COMMITTEES

- The Technical Advisory Committee
- The Advisory Committee on Epidemiology
- The National Advisory Committee on Immunization
- The Committee to Advise on Tropical Medicine & Travel

UNIVERSITIES

- [illegible]

INDUSTRY

- medical research
- diagnostic products
- treatment products
- surveillance equipment
- medical information

VOLUNTARY AGENCIES

- [illegible]

PATIENTS/CLIENTS

- [illegible]

REGULATORS

- [illegible]

OTHERS

- [illegible]

PUBLIC HEALTH

- [illegible]

HEALTH CARE DELIVERY

- [illegible]

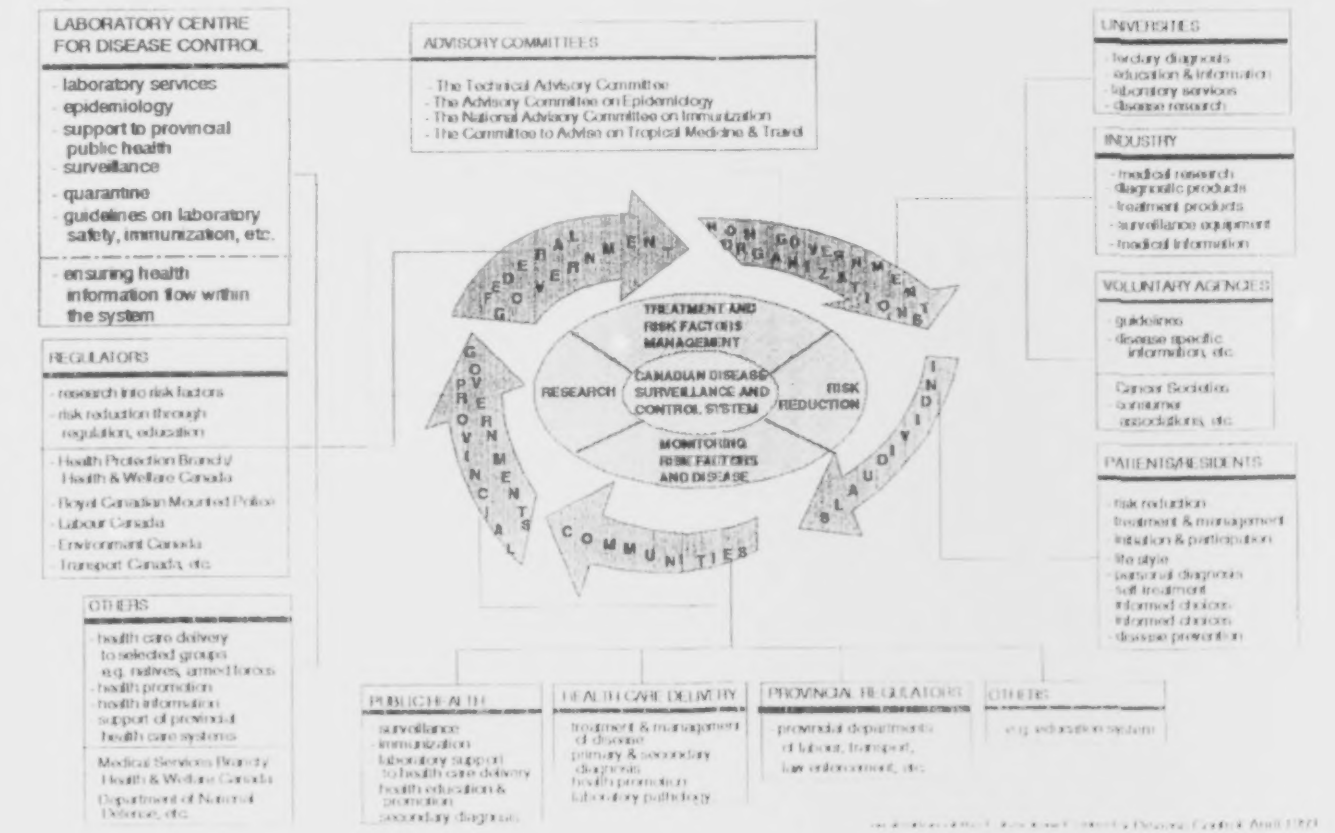
PREVENTIVE MEDICINE

- [illegible]

OTHERS

- [illegible]

FIGURE 2. DISEASE SURVEILLANCE AND CONTROL SYSTEM - CANADIAN MODEL



There is no formal responsibility, within the federal system, for evaluating the health effects of its regulations and programs. Within Health and Welfare Canada, there exist a number of mechanisms for registering adverse reactions and post-marketing surveillance. However, these do not formally and objectively evaluate the overall health effects of regulations, and in particular, of regulations of other federal agencies.

LCDC'S Role in the Canadian Disease Surveillance and Control System

This section discusses an ideal role for LCDC given the current federal provincial/territorial responsibilities and examines its current role. The discussion is arranged according to the four broad components of the conceptual framework of the disease surveillance and control system, namely, research, surveillance, risk reduction, and treatment and management of ill-health. Because of the importance of "risk assessment" to LCDC and the Health Protection Branch, LCDC's role in risk assessment is discussed in more detail in a later section.

As mentioned before, LCDC's current role has evolved over the last 75 years or so in response to the changes in the disease surveillance and control mechanisms and changes to the health care and public health systems. LCDC is active, to varying degrees, in all four components of the disease surveillance and control system. It has also assumed the coordinating role mentioned in the last section.

Research

The research component is the knowledge-generation part of the disease surveillance and control system. Some of the tools which are used in this component are laboratory and clinical research, methods and protocols for epidemiological, population and environmental surveys, use of administrative information, analytical and simulation models, and cost-benefit-effectiveness analysis.

LCDC is not alone engaged in disease surveillance and control related research. Universities and numerous public and private sector research establishments play a major role in the research component.

Because of its national perspective and mandate, LCDC is well positioned to effectively identify the need for and undertake research which can benefit the entire disease surveillance and control system and reduce unnecessary duplication. Another potential advantage of LCDC involvement in the research component is to bring harmony in the Canadian surveillance and control system. Therefore, LCDC ideally has a legitimate role in the research area. This includes:

a. research and development of methods for identifying or more effectively identifying microbiological organisms suspected of causing illness;

b. research and development of epidemiological methods, models and protocols which can be used by all sectors involved in the surveillance of risk factors and diseases;

c. risk assessment methods and models;

d. methods and protocols for field epidemiological investigations; and

e. national guidelines for the control of infections in laboratories which deal with pathogens and for the use of health care workers.

As mentioned before, universities, and public and private sector research establishments have a major stake in this component. LCDC does not necessarily have to conduct the research on its own, but it has to evaluate research findings from all sources, develop consensus among all the key players and coordinate the development of guidelines. However, when there is a lack of research from other sectors, LCDC will need to undertake or commission the necessary research. This is particularly true for methods for identification and/or speciation of pathogens, or the emergence of new pathogens.

LCDC is currently involved in all the five areas mentioned above. For example,

> *LCDC's Bureau of Microbiology has developed methods for programmable automated inoculator/replicator designed to perform MIC testing of* ***N. gonorrhoeae****.*
>
> *The Bureau of Communicable Disease Epidemiology has developed and gives a training program for field epidemiologists. It is also involved in coordinating the development of national guidelines for immunization, which is used by the provinces and community public health systems in developing their policies and programs for immunization, and by individual physicians in providing care to their patients.*
>
> *The Bureau of Chronic Disease Epidemiology has developed a protocol and system for a database on childhood injuries which are serious enough to warrant a hospital visit. The Bureau along with Statistics Canada is also involved in the development of provincial cancer registries which are consistent with the International Cancer Registry. These databases and registries provide uniform information with known quality for epidemiological research and for the development of public policies.*
>
> *The Domoic Acid case study found that LCDC has developed a comprehensive reference on the Domoic Acid food poisoning.*
>
> *The Division of Bio-Safety provides a course on Bio-safety and containment of microbiological hazards in laboratories. This course is found to be useful by all the public health laboratories.*

LCDC has recently established a Risk Management Unit. It can play an important role in developing methods and models for risk assessment. As mentioned before, risk assessment is discussed in more detail in a separate section later in this chapter.

Surveillance

Surveillance is a vital part of any efficient and effective public health system. It involves ongoing monitoring or special epidemiological studies of risk factors and diseases. Monitoring communicable diseases makes a timely response for preventing or controlling epidemics possible. Monitoring non-communicable diseases and their risk factors can be used in improving education, prevention, control programs.

However, there are too many diseases and risk factors for LCDC, or for any single agency, to monitor on an ongoing basis. Therefore, what is important is that the Canadian system as a whole collects information on diseases, risk factors and health outcomes for analysis, when needed and that there is little duplication in surveillance efforts and studies. This requires effective coordination.

In Canada, provinces/territories are responsible for the health care of its residents. The populations and resources of provinces/territories vary a great deal, yet they are potentially subject to similar diseases and have present in their environment the same risk factors. Timely epidemiological information is vital for them to respond to epidemics of communicable diseases and for developing prevention and health care programs. It would be inefficient for each province/territory to develop its own epidemiological data and methods, and national and international disease surveillance. A central agency like LCDC can compile the essential information and provide it to all provinces, thus reducing duplication within the system.

An important distinction to make here is between the collection and reporting of relevant information and surveillance. LCDC does not have to collect and process the information, if it could be done more effectively by others. For example, Environment Canada collects and reports on ultra-violet readings. LCDC can acquire this data for correlating with skin cancer and other adverse health outcome. Similarly, The Hospital Medical Records Institute (or the proposed Canadian Institute for Health Information) could continue to collect information on hospital morbidity and LCDC could use it for epidemiological studies.

The case studies on Tuberculosis, the Children's Hospital Injury Research and Prevention Program (CHIRPP), and the Domoic Acid Food Poisoning episode confirm that LCDC currently is active in national level surveillance programs. However, there are some questions about what involvement an agency like LCDC should have in collecting and publishing information if it does not add any "value" to the information. For example, what value is added by LCDC in maintaining the CHIRPP database. No doubt its contribution in the initial stages of the program, in the development of protocol and data capture instruments, was important. However, it is valid to ask whether the ongoing data collection could be equally effectively done by others, releasing valuable LCDC resources to undertake other projects.

The evaluation noted that the Bureau of Chronic Disease Epidemiology is active in studies related to cancer, aging-related diseases, children's injuries and some environment-related diseases. It is not as active in

heart and lung diseases, but Statistics Canada is. However, the ongoing collaboration between LCDC and Statistics Canada ensures that there is little duplication between them.

The evaluation also noted that LCDC is not active in the surveillance of psychological (mental) diseases other than those related to aging.

As mentioned earlier, surveillance can also be used in evaluating effects of specific regulations and programs on health. For example it could be used in answering the following types of questions:

> *Has the use of unleaded gasoline in automobiles resulted in reduced health problems?*
>
> *Have health promotion programs (like Participaction) led to improved health?*
>
> *Have the regulations on blood products led to a reduced risk to the health of Canadians?*

The federal government has the mandate to regulate certain industries and impose certain standards (e.g., food safety regulations and standards, reporting requirements of the Workplace Hazards Materials Information System (WHIMIS), medical devices, etc.) to prevent and control unfavourable health outcomes. Some programs; e.g., law enforcement programs, etc. which are designed to achieve non-health objectives, may have beneficial or adverse effects on human health. While regulations and standards are based on expectations from scientific information, their actual implementation may yield different results.

Regulating agencies monitor the risk factors present in the substances and industry they regulate. Many of them also have systems in place to report and document adverse health reactions resulting from their regulations. However, there is a need to monitor actual exposure to risk factors in order to assess the health effects of these regulations in an objective way.

The effects of many public sector regulations and programs may not be noticeable for a number of years. For example, a campaign urging people to reduce their exposure to ultra-violet rays may not result in reduced number of skin cancers for many years. However, it is important that information on the exposure to ultra-violet rays and skin cancer is maintained on an ongoing basis for an eventual evaluation of the program.

LCDC should ideally have the mandate to collect and maintain risk factor - health effects information and conduct such evaluations. However, it would not be practical for LCDC to evaluate the health effects of every federal regulation and program. In any event, regulating agencies and program managers would have to monitor effects (including health effects) of their programs and make changes to regulations and programs as necessary. LCDC could develop methods for, promote and participate in the evaluation of health effects.

From time to time, provincial public health systems need assistance in conducting field epidemiology studies. For example, in the case of the Domoic Acid Food Poisoning episode (1990) in the Atlantic provinces and Quebec, there was need for conducting epidemiological studies to identify cases of food poisoning which were potentially linked to the suspected mussels. LCDC with its field epidemiologists was in an excellent position to participate in this endeavour. Its contribution to this investigation was well received by all key players.

As mentioned in chapter two, LCDC provides a field epidemiology training program. This training program forms an important part of LCDC's surveillance activities. The trainees do their field placements with LCDC or with provincial health agencies. During the field placement, the trainees get hands-on experience on disease surveillance. LCDC's Field Epidemiology training program is parallel to the Centers for Disease Control's (CDC) program in USA. The USA program has also proven to be successful in helping state public health departments as well as in providing excellent training to public health professionals.

Risk Reduction

Risk reduction is mainly the responsibility of the public health and the health care systems, education, industry, regulators, media and individuals. The evaluation found that the only area where LCDC has a direct role in risk reduction is the administration of the Quarantine Act. Its role in other risk reduction activities is that of the development and provision of information. Such information could be used in developing policies, programs, and activities as well as in evaluating their effectiveness.

LCDC took over the administration Quarantine Act since the last evaluation. Medical Services Branch still provides field services for the Quarantine Program. The Act is considered to be antiquated. With the modern rapid air transportation and increased international traffic, interception of "ill" persons at the borders is almost impossible. It is left to individuals and (if they go to a physician) to the attending physician to report illnesses, which might come under the Quarantine Act and Regulations, to public health officials. More serious cases, where a hospital visit or hospitalization is necessary, have a better chance of being followed. Nonetheless, the traditional approach of isolating the potential source (infected individuals) to prevent further infections is replaced by tracking down the persons who may have been in contact with the suspected source to ensure that they receive appropriate medical attention and information.

Results of communicable and non-communicable disease epidemiology studies are useful in health promotion and education. In USA, the Centres for Disease Control are themselves involved in health promotion initiatives. Its communicable disease and chronic disease programs are integrated with health promotion. This ensures that the results of CDC epidemiological studies are used in health promotion.

Within Health and Welfare Canada, health promotion is the responsibility of the Health Promotion Directorate of the Health and Social Services Branch. The evaluation did not see any evidence of

continuing joint ventures between LCDC and the Health Promotion Directorate. Also, provincial health officials did not mention much contact between them and the chronic disease epidemiology program.

Treatment and Management of Ill-Health

LCDC has no direct role in the treatment and management of diseases. However, it provides laboratory services and advice on the management of outbreaks of infectious diseases, when requested.

LCDC provides laboratory services for the identification and speciation of microbiological agents suspected of causing illness. This service is provided through its National Laboratories (part of LCDC) and National Centres (external laboratories which provide similar service through contractual arrangements). With the increasing degree of sophistication available at the community, hospital and provincial laboratories, the need for identification services is getting smaller and smaller. However, LCDC's services are still needed for rare organisms or where it has the expertise provinces do not have .

From time to time, provinces need advice on the management of disease outbreaks. LCDC, if requested, provides such advice to provincial and local health authorities. For example,

> *LCDC provided advice to public health officials in Ontario and Quebec in the management of the recent meningococcal epidemic.*

LCDC's Role: Opinions of the Clients

All those who were consulted were asked about their views on the need for an agency such as LCDC. Almost all respondents felt that there is a need for a central agency like LCDC to conduct disease surveillance at the national and international level, coordinate the development of guidelines on disease surveillance and control (e.g., national immunization guidelines), coordinate consensus conferences, and provide back-up support to provincial public health systems (in particular in the area of microbiology laboratory analysis). They were very supportive of LCDC's field epidemiology training program.

Only two out of 80 external clients interviewed felt that LCDC was not needed. The remaining 78 stated that LCDC was needed. Six stated that the absence of LCDC would affect them significantly in a negative way, citing repercussions such as, *"chaos, major problems, absence of federal role, lack of policy guidance, added dependency on CDC, lack of coordination between provincial labs, potential duplication of activities in provinces"*, etc.

During the course of the consultations, questions arose concerning the appropriateness of LCDC's role in collection, analysis, and dissemination of certain data, e.g. CHIRPP data. The question was whether LCDC should get involved in activities where no value was being added by their highly skilled staff, and whether such work could be done by individuals with statistical backgrounds alone, e.g. Statistics Canada, (or by the proposed Canadian Institute of Health Information).

There were a few who felt that LCDC should not involve itself in the chronic disease epidemiology. They felt this was more a matter for universities and health promotion areas.

Many described LCDC's role as one of the "eleven members" of the federal provincial public health organizations. They felt that all members have equal contribution to make.

Based on the system analysis, and the information gathered from consultations and other sources, the evaluation concluded that there is a need or an agency like LCDC in the Canadian disease surveillance and control system; and that LCDC's ideal role should include:

- **the development or coordination of the development of methods, tools and protocols for disease and risk factor surveillance, risk assessment, and risk management,**
- **the conduct of national level disease surveillance and international intelligence, and the conduct of special epidemiological and risk assessment studies,**
- **the promotion of and support to the evaluation/monitoring of the effects of federal regulations and programs on the health of Canadians,**
- **the development and provision of information which could be used in developing and implementing risk reduction policies and programs, and implementation of the quarantine program, and**
- **the provision of laboratory, surveillance and advisory support to provincial, territorial, community and regional public health agencies as well as other health care givers in their efforts of disease management.**

The evaluation also concluded that LCDC is currently involved in all activities mentioned above, except in the evaluation of health effects of federal regulations and programs, and that LCDC's clients and stakeholders agree with and support its ideal and current role.

Risk Assessment

Many public health policy and operational decisions deal with managing risks to human health. For example, *should infants receive routine immunization? If yes, what immunization and when? If not, then what would be the consequences to the infant and to the health care system?* Or, *should the system vigorously encourage women over a certain age to routinely ask for screening for breast cancer? What are the implications to individuals, the health care system and the society in either case? Should the use of seatbelts in cars be mandatory?*

Risk assessment is either used implicitly or explicitly in arriving at such decisions. The use of formal risk assessment techniques (quantitative

techniques including cost-benefit analysis, cost-effectiveness analysis, statistical estimation and demographic methods) in making such decisions is increasing. Perhaps, while risk elimination remains an ultimate goal, the disease control system is becoming more and more aware that risk management (reduction) may be a more attainable and, therefore, should be an immediate goal. Formal risk assessment techniques can provide more objective information to choose options for risk management.

Within the context of disease surveillance and control system, risk assessment is subdivided into *risk analysis* during which hazards are identified and their risks estimated, and *option evaluation* during which various "options" of dealing with the risk are developed and each option's value is analyzed. Two methods are typically used to identify health hazards: epidemiological studies of disease in human populations using epidemiological risk assessment (prevalence and incidence), and laboratory toxicological investigations of substances using consistent and random processes.

LCDC is active in risk assessment.

Firstly, there are a number of projects underway in all the bureaux of LCDC which contribute to the risk assessment efforts. These include, for example, the Breast Implant risk assessment study, the Canadian Farm Operator Mortality Study which looks at pesticides and cancer risk, reemergence and multi-drug resistance in tuberculosis, etc.

Secondly, in 1991, to bolster its involvement in risk assessment, LCDC established a Strategic Planning and Risk Management unit directly reporting to the Director General. The unit is still in its infancy and has not become fully operational. LCDC's goals and future activities in risk management (as outlined in "*Laboratory Centre for Disease Control, Tropical Health & Travel*, January 1992) are concentrated on:

- conducting leading-edge studies on communicable and chronic diseases, as bases for preventive and control-oriented interventions;
- explicitly defining national health goals and objectives, so that resources can be focused on achieving nationwide results;
- improving communications within the public health arena, so that existing knowledge of disease prevention and health enhancement can be applied effectively;
- conducting more health surveys to identify the population's disease burden and the prevalence of risk factors that can be modified; and
- developing useful measures of health outcomes for individual chronic diseases.

As a part of the consultation process, LCDC's external and internal clients and stakeholders were asked about LCDC's current activities in risk assessment and management and what they thought LCDC should be doing. Out of 100 respondents, only five were "familiar" and another ten were "peripherally familiar" with LCDC's efforts in the area of risk assessment. The remaining 85 were not familiar. Three of the five respondents supported LCDC's present role with statements, such as, "*LCDC should do the same things they are doing now*"; and "*LCDC should be the central location for Canada and be more involved in risk assessment*". Only two respondents were against LCDC's involvement in risk assessment.

When asked about what LCDC should ideally do in this area, the responses varied between those with no ideas to those offering several suggestions. Specific suggestions included: *conducting more studies on the population to determine adverse reactions to selected vaccines; investigations of harmful effects of environmentally polluting substances; providing national direction for provincial and community goal setting; the effect of smoking; surveillance of cardiovascular diseases, diabetes, congenital anomalies in child birth, etc.*

The respondents were unanimous in their view that risk assessment should be based on Canadian data when appropriate and available. But they were not averse to using information from USA and other countries as well.

Some external respondents also noted that the federal role involves only health **risk assessment.** They emphasized that health care is a provincial responsibility and that **risk management**, e.g. vaccinations, should be left to the provinces. From the perspective of these clients, the risk management referred to treatment and management of ill-health, and did not include risk reduction through regulation - a legitimate federal function.

However, as discussed in the previous section, LCDC has a legitimate contribution to make in developing methods, models and procedures for risk assessment and risk management, and making them available to federal, provincial and other public health agencies. It is, perhaps, not mandated for conducting research on treating individual patients, but it can develop methods for assessing the mass application of such techniques. For example, LCDC does not have the mandate to conduct clinical trials on drugs, but it could develop methods to estimate the costs and effects of the use of drugs in the patient population.

About half of the respondents consulted on LCDC's role in travel medicine felt that LCDC has or should have a role in providing advisory services to Canadians travelling overseas on potential health risks in the countries they plan to visit. The rest of the respondents were either of the opinion that LCDC services are not needed in this area or that LCDC is not qualified to do this, or had no comments.

In conclusion, LCDC has a legitimate contribution to make in the area of risk assessment. While risk management may be the

responsibility of federal, provincial/territorial and local public health officials, health care givers and regulators, LCDC could provide the tools, information and advice for risk management.

Client Expectations and Satisfaction

LCDC has a varied mix of clients. Its direct clients include provincial epidemiologists, provincial public health laboratories and researchers in the chronic and communicable diseases. Its services and products reach a much wider segment of the disease surveillance and control system. For example, community and regional medical officers of health receive LCDC's publications, and advice on the identification and management of potential spread of communicable diseases. They depend on LCDC's surveillance reports for information on disease patterns elsewhere. Hospital and private practice physicians benefit from information in the immunization guide. Canadians travelling abroad benefit from information on diseases prevalent at their destinations and recommended immunizations. Information developed by LCDC reaches its clients through regular publications, bulletins, special reports and media.

The clients of the Bureaux of Communicable Disease Epidemiology and Microbiology and the Division of Bio-Safety tend to be provincial epidemiologists and provincial laboratories. Normally, community and regional public health agencies, hospitals and other primary care institutions receive LCDC services through their provincial public agencies.

The clients of the Chronic Disease Epidemiology tend to be engaged in research, disease prevention, health promotion and regulation. They usually work in universities, hospitals, health care professions, voluntary agencies (e.g., Canadian Cancer Society, Canadian Diabetes Association, etc.), governmental regulating bodies, and media. Provincial public health agencies are, generally, more active in the management of communicable diseases and less in the management of chronic diseases.

The clients of the Bureau of Microbiology and the Office of Biosafety, generally, are public health laboratories and microbiology laboratories.

While LCDC provides "products and services" to its clients, its relationship with them is that of a partner and at the same time as coordinator or leader of specific initiatives. LCDC needs to know, on an ongoing basis, what its clients want and what they may need in the future. LCDC achieves this through a number of national advisory committees, e.g., Advisory Committee of Epidemiology, Technical Advisory Committee, National Advisory Committee on Immunizations, and Canadian Advisory Committee on Tropical Medicine and Travel. Members of ACE and TAC are provincial epidemiologists and public health laboratories. These committees advise LCDC and at the same time provide LCDC an opportunity to know the changing needs of its primary clients, the provinces.

All of those who were consulted were asked what products and services they received from LCDC, which of these services they could not obtain elsewhere, and to what extent their expectation were met.

LCDC's clients expect it to: maintain a national picture of disease surveillance, carry out international intelligence, develop common data banks, set standards for data collection, ensure that data are uniformly collected, provide (publish) more information, provide national training in the area of bio-safety, field epidemiology and specialized laboratory techniques, and support provincial public health system by conducting or participating in outbreak investigations and providing timely specialized laboratory analysis. They also want LCDC to provide proficiency testing for microbiological tests, supply reagents which are not commercially available, and conduct risk factor surveys. The list goes on.

All these services are consistent with LCDC's mandate and role. With active consultations with its clients through advisory committees, LCDC is in tune with the needs of its clients. It has been able to discontinue those products and services which are no longer required by its clients and develop new products and services which they will need. As an example, as provincial, hospital and community public health laboratories have become more self sufficient in the identification of many pathogens, LCDC has vacated those areas. Also, with the reemergence of multi-drug resistant tuberculosis, it has put more emphasis on research and development in this area.

LCDC's clients do not see it as a source of world literature on disease surveillance/control. A large majority of them stated that they have adequate access to world literature through their own electronic literature retrieval systems, networks, and contacts with well reputed institutions such as the Health Science Research Centre, CDC, and the Pasteur Institute. However, they indicated that certain LCDC publications are quite important to them, namely: Canadian Communicable Diseases Report (CCDR), Chronic Disease in Canada, Notifiable Disease Report, unpublished information on the computer bulletin board, and Canadian guidelines (e.g., guidelines on immunization).

Almost all of the respondents stated that they receive some services and products which could not be obtained from other sources. These included, in particular, international intelligence, national surveillance information, national guidelines and laboratory support for specialized analysis.

All stakeholders stated that LCDC is of great value to them in carrying out their responsibilities. A majority of them expressed their satisfaction with the quality of the services. However, about 60% of them complained about delays in delivering some services such as publications, test results, and data analysis. Some had experienced difficulties in contacting proper experts for obtaining advice in times of emergency. They thought that LCDC should have backup expertise available in case of emergency.

A majority of them also felt that LCDC's communication with its clients could be improved. This observation is consistent with the conclusions of other LCDC internal reviews. However, almost all LCDC clients agreed that LCDC has changed in the last few years and changed for better. It has become more responsive than before. They would like LCDC to continue to do what it is doing currently and provide a more timely service.

LCDC clients who receive services on bio-safety were very satisfied with the services. They were also supportive of LCDC's training program as well as workshops.

LCDC's field epidemiology training program also received support and appreciation. There are a few past graduates of this training program who are now working within provincial public health organizations. Some epidemiologists from smaller provinces noted that they have almost none to very limited access to field epidemiologists. They felt that smaller provinces are in greater need for support from a central agency like LCDC. They feel that each province should have a field epidemiology trainee.

Since the last evaluation, LCDC has discontinued its services in diagnostic bio-chemistry. This has not posed any problems to provincial public health systems. A few characterized that LCDC has become primarily a medical microbiology institute, with the exception of the Bureau of Chronic Disease Epidemiology. A few of those consulted suggested that LCDC should get out of chronic disease epidemiology. They felt that there are many other organizations (e.g., universities, medical research establishments, health promotion organizations, etc.) which are better placed to work in this area. This opinion is further discussed in chapter six, "alternative organizational arrangements."

There were three specific areas where LCDC's clients want more services or improved services; namely, more field epidemiology support and improved timeliness and back-up of expertise. LCDC would have to increase the number of field epidemiology trainees, if it is to meet the needs of all provinces. To improve its timeliness and provide back-up of expertise, it may need to free up resources from other activities with low priorities or those which could be done equally efficiently by other organizations.

Before embarking on long term projects requiring considerable resources, LCDC needs to determine whether the projects is essential, the project has to be undertaken internally by LCDC, and if it can be done by others outside LCDC.

In conclusion, expectation of LCDC's clients are consistent with its ideal and current role. LCDC has the opportunity to change and has changed its activities, products and services to meet the changing needs of its clients.

LCDC's clients are generally satisfied with the services and the quality of services they get. However, about 60% complained about

the delays in the service. They also felt the need for a better communication from LCDC and back-up of expertise in case of emergencies.

Gaps and Overlaps in the System

This section discusses gaps and overlaps in the Canadian disease surveillance and control system and what modifications to LCDC's role are necessary to eliminate gaps and overlaps.

The evaluation did not find any serious gaps in the system. Only a small number of stakeholders and clients identified some gaps in the system. These included: *absence of a National Centre for typing of some food borne pathogens, (e.g. Bacillus cereus and Clostridium perfringens); research on and monitoring of occupational diseases; graphic presentations on disease surveillance data for presentations; information on congenital anomalies; post maternity surveillance; registries for drugs and for medical devices; diagnostic kit evaluation data; and cardiovascular data.* Some of these activities may fall outside the mandate of LCDC.

Most of the respondents took this opportunity to state that LCDC services need to be improved by asking for: more in-depth data analysis; more effective coordination; faster response to requests for services; more research and development; and more efforts in training and education.

Most clients and stakeholders felt that there is little overlap or duplication . However there were a few exceptions such as: a) AIDS serology has been done by LCDC and also done in the province of Quebec since 1986; b) Hepatitis B serology done by LCDC and other provinces; c) the existence of two parasitology centres; and d) LCDC's printing of brochures which are also printed by the provinces, (e.g. travel medicine). Also, some respondents commented that a few LCDC services (analysis of syphilis, and serology) should be suspended.

The main products of LCDC are surveillance, risk assessment and risk management information. There are many federal, provincial and public and private sector agencies engaged in developing similar information. For example, hospital morbidity data form a part of disease surveillance information. Statistics Canada as well as Hospital Medical Records Institute of Toronto have a mandate in compiling and disseminating such information. There may be some overlap between LCDC and these agencies.

Universities, teaching hospitals, and some non-governmental agencies are engaged in epidemiology of chronic diseases, for example, epidemiology of breast cancer. Such duplications are inevitable and in some circumstances are beneficial to the advancement of knowledge. What is needed to avoid unnecessary duplication is more effective communication and coordination between these agencies.

The evaluation found that LCDC collaborates with many non-governmental organizations, for example, with the (Canadian) National

Cancer Institute and the Canadian Cancer Society in the conduct of research, and with the Canadian Lung/Thoracic Association in developing guidelines on tuberculosis. Representatives of such organizations felt that there was no duplication between the LCDC's programs and theirs. Some other non-governmental agencies were not up to date on LCDC's activities in their area of concern. While there was little chance that these agencies would have programs which overlap with LCDC's activities, there was a gap in their knowledge about LCDC activities.

While there are no significant overlaps at this time, with the establishment of the Canadian Institute for Health Information there is a potential for overlapping activities. Also a similar potential exists for duplication between LCDC and agencies like Statistics Canada and Canadian Coordinating Office for Health Technology Assessment. However, these potential for duplication could be turned around to an advantage by better coordination and collaborative projects.

In conclusion, there are no serious gaps and overlaps in the system. However, a few stakeholders have identified a number of areas which they consider gaps. There is a potential for LCDC and other agencies to have overlapping activities. However, this potential could be reduced with better communication and coordination.

Consultations did not reveal the need for any modifications to LCDC's programs to meet the needs of its clients.

chapter four

findings and conclusions: technology transfer

This chapter presents the findings and conclusions about LCDC's efforts in transferring technologies it has developed and additional mechanisms LCDC should put in place for transferring technologies in the future.

The technology transfer issue was included in this evaluation as a follow-up review to the last evaluation study (1984-85).

Evaluation Approach

A limited review of Canadian government documentation concerning technology transfer activities was carried out to establish an understanding of the issue. This was followed-up with consultations with specialists in the technology transfer specialty area and with a number of Health Protection Branch managers.

The LCDC Program Contact Officer was then requested to provide information on technology transfer activities of the program. Where the provided information was not adequate, specific projects of interest were followed-up by visit or telephone contact with individual investigators or managers. Additionally, the program stakeholder/clients consultation protocol contained the following two questions related to technology transfer:

1. During the last 5 years, what technology (methodology/processes) uniquely developed by LCDC has your organization adopted for use?

2. Is any of the technology adopted from LCDC still being used by your organization?

Introduction and Background

The stated objective of the Canadian Government in technology transfer is to transfer technologies developed in government laboratories and institutions to the private sector or to stakeholders for timely commercialization and/or for use in the improvement of Canadian competitiveness.

LCDC functions in the Canadian disease surveillance, diagnostic and control system as a high level reference/advisory organization. This is especially true in the area of diagnostic microbiology. Generally, any specimens referred to LCDC have already been examined or partially identified by one or more public health laboratories. These specimens

are sent to LCDC because they are either difficult to identify or need categorization at a level not considered routine. Such identification or categorization may require the use of expensive state-of-the-art technologies not normally available in all laboratories or it may require development of new technologies. LCDC, therefore, works in an environment where the opportunities for innovation and/or development of diagnostic products, technologies and methodologies are plentiful.

The use of up-to-date diagnostic technologies is important in disease control. Wider use of such innovative technologies could lead to cost reductions to the health system. Some of the technologies developed at LCDC could also have commercial value. While the main focus the evaluation was on technologies generated in the laboratory component of LCDC, examples of transferable technologies from other parts of LCDC were also reviewed.

While LCDC tends to work in an environment where innovation occurs fairly frequently, **it should be emphasized that LCDC's mission is that of a service organization to its public health stakeholders, rather than that of a research organization**.

Definitions

For the purpose of the present review, the following definitions will apply:

Technology: Any diagnostic product or diagnostic methodology, including laboratory equipment and computers or associated software. In the area of disease surveillance any unique software and processes would be included.

Intellectual Property (IP): Any technology (methodology, equipment, unique software, or processes) which are substantially owned through invention, or substantive value added modification. In the normal case, intellectual property is owned through patents.

Technology transfer: Normally, technology transfer should result in the recipient being in complete possession of the technology after a specific period of collaboration. The recipient should be able to independently manufacture the diagnostic product or independently carry out the methodology. This does not eliminate the possibility for further cooperation with LCDC to improve the products transferred.

Scope and Limitations of the Definitions for the Purpose of the Evaluation: A conservative definition (hard technology transfer) would reserve technology transfer to only those IPs which have been invented or developed by an organization or an individual and which can be protected by patents or similar processes. Such technology can then be transferred to the private sector for commercialization to increase Canadian competitiveness. Such a narrow definition is perhaps not justified in the current LCDC study, since the main purpose of the technology transfer here is not commercialization but to spread the use of state-of-the-art technology in the Canadian disease surveillance and control system. Such technology transfers without commercialization

(soft technology transfers) have the potential for producing substantial public goods at the national level.

The evaluation, therefore, examined other processes and products developed by LCDC which, if transferred to its clients and stakeholders, would result in substantial public good. However, this examination included only those processes and products which are the intellectual property of LCDC.

The term technology transfer does not include transfer or diffusion of knowledge through learned publications, information dissemination, training, and consulting based on the application of published knowledge. Such activities are no less important and beneficial to Canadian disease surveillance and control system, but they are not technology transfers. Therefore, supplying sub-cultures and other standard reference materials would not be considered as a technology transfer.

The above modification to the definitions appears in essential agreement with those implied for technology transfer and knowledge transfer (knowledge diffusion) in the recent publication from LCDC (1992, Laboratory Centre for Disease Control, Minister of Supply and Services Canada, Cat. No. H49-80/1992E).

Technologies Developed

The following list provides examples of technologies developed by LCDC which satisfy the definition of technology and which can potentially be transferred to program stakeholders (draft Memorandum of Agreement Between National Research Council Canada and Health and Welfare Canada):

1. Programmable automated inoculator/replicator.
   Inventor: J. Dillon/S. Lighstone/K. Yeung
   Patent: US, Canada
   License: TBA (in process).

2. Heterohybridomas Secreting Human Mab against Haemophilus influenza.
   Inventor: B. Brodeur/J. Hamel/D.Martin
   Patent: Canada
   License: Nil.

3. Mab for identification of Haemophilus influenza Type B.
   Inventor: B. Brodeur
   Patent: US
   License: Nil.

4. Mab for identification of Haemophilus influenza.
   Inventor: J. Hamel/S. Montlaisir
   Patent: US, Canada
   License: Nil.

5. Use of synthetic glycolipids in serodiagnosis of tuberculosis.
   Inventor: A. Laszlo

Patent: US, Canada
License: Nil.

6. Mab directed against S. pneumonia.
Inventor: B. Brodeur
Patent: US, Canada
License: Global Tek Inc. (in process).

7. Mab directed against Bordetella.
Inventor: B. Brodeur
Patent; Trade Secret - early disclosure
License: Synthetic Peptides Inc. (in process).

8. Mab for the detection of Mycoplasma.
Inventor: B. Brodeur
Patent: Canada
License: Nil.

9. Computer program for Canadian Hospitals Injury, Reporting and Prevention Program (CHIRRP).
Users: 13 CHIRRP hospitals.

The consultations with stakeholders in positions to adopt LCDC invented technologies indicated that they do not consider LCDC as a significant source of such technology. This finding is perhaps not surprising if it is considered that LCDC is reported to work mainly in areas not currently being done by the stakeholders. LCDC's activities in the area of knowledge transfer as a clearinghouse or as a teaching institution were, however, highly valued by almost all respondents, comments such as: *LCDC provides the best specialized training for newly appointed supervisors (in provincial laboratories) available anywhere, LCDC has increased the size of the data base for speciation of microorganisms by specific methodologies, LCDC is a major source of biotechnology and other training*, and *if we want to acquire a new technology or reagent we consult LCDC and buy from the recommended source if LCDC can not supply* were common.

On the other hand, several provincial health agencies stressed that LCDC similarly benefits from knowledge exchange with its provincial partners, the adoption by LCDC of software and various laboratory methodologies being specifically mentioned.

In conclusion, LCDC has developed a substantive number of technologies that have been transferred, are being transferred or can potentially be transferred to various national and international stakeholders. As expected, most of the projects cited involved the laboratory component of LCDC and consisted of diagnostic products, methodologies or diagnostic equipment.

LCDC's Technology Transfer Activities

There was considerable evidence that technology transfer and technology transfer type activities, as well as knowledge diffusion activities, occurred in many, if not most, operational units throughout LCDC. Many of these activities appeared to occur in a relatively

unstructured and informal manner and operate through the national and international peer or stakeholder science networks.

However, the evaluation was unable to find any evidence of a formal coordinated technology transfer program or an officer or office that had a coordinative or advisory role for such a program within LCDC. There were no detailed descriptions of technology transfer projects. There also appeared to be an absence of a clear definition as to which projects should be included under the term, "Technology Transfer". There was a lack of information on whether the transferred technology is currently being marketed by the commercial recipient (partner) or how many Canadian program stakeholders are using the transferred technology.

HWC is currently in the process of signing a formal Memorandum of Agreement (MA) with the Intellectual Property Services Office (IPSO) of the National Research Council Canada. This MA will provide a formal mechanism for marketing transferable technologies invented by LCDC.

LCDC is well connected to the national and international public health science communities. Thus, information on technologies emerging from its laboratories is widely publicized. LCDC has used this network to disseminate the technologies it has developed to its stakeholders. However, the promotion of inventions through this network can limit the use of the technology in that a competing technology marketed by a private sector company with the customer service infrastructure may soon result in discontinuation of the use of technology marketed by LCDC.

It is important to acknowledge that LCDC has developed a number of potential transferable technologies. However, before these technologies enter the commercial market, they are subject to pressures from competitive products which may be promoted by companies with dedicated market development, marketing and after sales service infrastructure. It would be difficult for an organization like LCDC to develop and maintain similar infrastructure.

In conclusion, there are a number of technology transfer type activities currently going on in LCDC. Some technologies have been transferred and others are being transferred. However, LCDC has not yet established formal technology transfer program. A Memorandum of Agreement between Health and Welfare Canada and the Intellectual Property Service Office, when signed, will provide this formal process.

Additional Mechanisms Needed

This section discusses additional mechanisms which are needed for LCDC to improve its technology transfer process.

As discussed before, not all the innovations resulting from LCDC's work fall under the strict definition of commercially exploitable technologies. Further, if these commercially non-exploitable technologies were transferred to its clients, Canadian disease surveillance and control system and, consequently, the Canadian public would benefit. Therefore,

LCDC needs a clear definition of and a policy on technology transfer for use within LCDC. Its definition of transferrable technologies should be wider than the one used for commercially exploitable technologies. Such a broad definition would benefit Canadian disease surveillance and control system.

LCDC further needs a formal internal process and a designated responsibility for the management of technology transfer. The objective of this coordination is to facilitate processing of potential technology transfer projects and tracking successful projects. Such a centralized responsibility can also provide information on the technology transfer process to LCDC employees.

As mentioned in the preceding section, HWC is in the process of signing a Memorandum of Agreement with ISPO. This memorandum will provide a process which LCDC can use to transfer commercially exploitable as well as non-exploitable technologies to the public sector and to its partners and clients.

LCDC needs to develop its own definition of technologies which can be transferred to the private sector and to its partners and clients. The Memorandum of Agreement with Intellectual Property Service Office, would provide LCDC with a process for transferring newly invented technologies.

chapter five

findings and conclusions: cost recovery

The last evaluation study of LCDC recommended that all of LCDC publications, training courses and evaluation of commercial products, with the exception of those services identified as essential, should be considered for inclusion in a cost-recovery system. This chapter discusses the efforts made by LCDC, since the last evaluation, to recover costs, the results and consequences of these efforts, and the identification of other LCDC's products and services that could be cost recovered.

LCDC Publications

LCDC has four routine and five occasional publications. It also publishes "issue papers" and "risk communications projects." The routine publications include: the biweekly *Canada Communicable Disease Report (CCDR)*, the monthly *Chronic Diseases in Canada (CDIC)*, the quarterly *Laboratory Safety Listings* and the annual *CHIRPP Technical Reports*. The occasional publications include: the *Canadian Immunization Guide, Infection Control Guidelines, Case Definitions for Reportable Communicable Diseases, Guidelines for Diagnosis and Treatment of STDs* and *Laboratory Biosafety Guidelines*. Examples of "issue papers" include *Tobacco Smoking Issue* and *Economic Burden of Illness in Canada*. Examples of "risk communication projects" include *Flu Immunization, Food Safety,* and *Biomedical Waste* cheque inserts.

LCDC charges for only one of its publications: the Canadian Communicable Disease Report which was formerly titled the *Canada Diseases Weekly Report (CDWR)*. In addition, LCDC and Statistics Canada have jointly published a mortality atlas for Canada which is sold at a price.

In 1991, LCDC mailed a questionnaire to all subscribers of CDWR to determine 1) their willingness to pay for CDWR, 2) the degree of satisfaction with a biweekly rather than a weekly issue of the publication, and 3) the number of subscriptions each subscriber would like to order. In reality, the questionnaire was an order form with questions added to gauge reader satisfaction.

Forty five percent of the subscribers responded to the questionnaire. The responses revealed that 1) 60% would not be willing to pay for CDWR,

2) 94% would be satisfied with a biweekly Report, and 3) 84% would only need one copy.

Based on these results, which were published in the CDWR September 28, 1991 issue, LCDC announced that starting January 1, 1992, CDWR would be published as the Canadian Communicable Disease Report (CCDR) on a biweekly basis at a cost of $2.50 per issue or $60.00 per year. Consequently, LCDC received orders for 2,200 paid subscriptions. In addition, LCDC pays for 300 subscriptions for distribution to its key clients/stakeholders. The marketing of CCDR has been transferred to the Canada Communication Group.

The cost recovery has dropped the circulation of CCDR from 11,800 to 2,500. This reduction has also diminished LCDC's ability to reach its secondary and tertiary clients and to keep them informed. LCDC will have to develop alternative mechanisms to reach its clients in order to provide them with up-to-date surveillance and other information.

LCDC has added CCDR to its "FAXLINK service" in order to provide public and professionals more access to the CCDR. The FAXLINK offers CCDR free of charge to any person with an access to a fax machine. Users are offered a choice between a current issue of CCDR, an index to previous CDWRs and archival access to all documents. The FAXLINK seems to defeat the purpose of cost recovery. You pay for CCDR, if you subscribe; you get it free, if you use FAXLINK.

LCDC considers FAXLINK as an experimental project, the service is not known to many of its clients/stakeholders. If this free service becomes well known and well used, it is unlikely that the number of paid subscriptions could be maintained at the current level.

Most of LCDC's publications, although available to the general public, have a small group of interested readers, mostly professionals working in a specialized field. Many of these publications also appear in learned journals as articles. These publications are not suitable for cost recovery. For example,

> *Guidelines for Diagnosis, Management and Treatment of Sexually Transmitted Diseases in Children, Adolescent and Adults. These types of publications are considered to be essential by many of LCDC clients/stakeholders and not a suitable for cost recovery.*

Other routine LCDC publications, such as the monthly Chronic Diseases in Canada, Laboratory Safety Listings and CHIRP Technical Reports have a wider readership. However, LCDC has not yet considered these publications for cost recovery.

Training Courses

LCDC offers training courses in biosafety, field epidemiology, laboratory mycobacteriology, etc. In addition, it provides special workshops on bio-hazards cabinet operations.

LCDC charges a fee of $300 for its 3-day Biosafety Principles and Practices course covering safety in biomedical laboratory. This course is offered annually and attended by about 20 persons. The course is accredited by the Canadian Society of Laboratory Technologists and the Canadian College of Microbiologists for continuing education credits. Lecturers of this course are experts in different biosafety fields. The course is mainly attended by managers and technicians from Canadian and international agencies.

The Office of Biosafety also holds special workshops on the selection, installation, design, and use of bio-hazard cabinets. Participants get a chance to discuss their own requirements for bio-hazard cabinets and obtain advice from Office of Biosafety during the workshops. These workshops are held when sufficient requests (20 or more) have been received. There are generally two to three workshops every year. However, in some years there were no workshops. The workshop is offered free. Participants have to pay for their own travel costs. If the workshop is held outside Ottawa, a small charge is levied to recover the cost of the travel of LCDC personnel.

The trainees for the one-year field epidemiology course are employed by LCDC throughout the duration of the course including the field placement phase. The course can be characterized as "in-service training" and not subject to cost-recovery. The arrangement of this course is similar to the one offered by the Centers for Disease Control in Atlanta. The LCDC course is appreciated by all provincial public health officials. The course has become a part of the coordinating mechanism for the Canadian disease surveillance and control system.

The last evaluation identified those training courses, which are given as part of LCDC's laboratory services, as candidates for cost-recovery. Various laboratories of the Bureau of Microbiology provide training courses, workshops and opportunities for professionals from Canada and elsewhere to work at the laboratories as a part of their studies at other universities. LCDC has not made any attempts to recover costs on these courses. The following are examples of such training courses:

1. *National Laboratory for Immunology (NLI) has been recognized as a teaching laboratory by the Schools of Graduate Studies and Research of both the University of Montreal and the University of Ottawa. Students studying at the NLI are financially supported by various granting agencies e.g., Medical Research Council.*

2. *Workshop on the identification of anaerobes given at the Royal Victoria Hospital followed by bench training to staff members from the Hospital.*

3. *International course on Tuberculosis bacteriology sponsored by the World Health Organization.*

Commercial Products: Reference and Diagnostic Services

Reagents and Reference Substances

LCDC has never charged for reagents it provides to Provincial Laboratories or other clients. Approximately 4 years ago, the Diagnostic Reagents Division was dissolved, at the time LCDC's supply of reagents became a non-priority strategy.

At present, LCDC National Laboratories and National Centres supply reagents that are vital but which either are not available commercially or are available commercially but are of not sufficiently high quality for use by the public health laboratories. Diagnostic and therapeutic reagents are currently supplied to provincial, hospital and other public health and research laboratories. There are numerous such reagents to list here. Examples of reagents supplied include:

1. Influenza typing sera (current strains)
2. Influenza current strains (antigen)
3. parvovirus B19 antegens for EIA
4. Standard strains of herpesvirus 1 and 2
5. Selected arbovirus typing sera and type strains
6. Selected *Mychobacterium* sp.
7. *Campylobactor* sp.(polyclonal) typing sera
8. Chlamydia strains
9. *N. Gonorrhoeae* reference strains
10. Hetermyeloma cells fusion partners
11. Anaerobic and aerobic bacterial cultures for use in reference activities in provincial and hospital laboratories.

No cost recovery attempts have been made by LCDC for reference or diagnostic services since the last evaluation. LCDC's clients consider these reagents as essential.

Diagnostic Services and Proficiency Tests

LCDC National Laboratories and National Centres provide laboratory services for the identification and/or speciation of pathogens and proficiency testing for quality assurance. LCDC does not recover costs for these tests.

Samples for these tests are collected in conjunction with treatment and management of patients. They come to LCDC through provincial public health laboratories. There is some question as to whether the provincial health care systems should pay for these services or not. Because the federal government shares the cost of health care through its health care financing program, charging for diagnostic services might not result in significant recovery of costs. Also, it may adversely affect LCDC's leadership and excellence in laboratory services.

Heads of many provincial laboratories said that they would be willing to pay for the tests. However, they observed that LCDC's expertise and reference material is developed from samples provided by provinces. Provinces may wish to institute a charge for the samples they provide to LCDC. In any case, if LCDC begins to charge for the diagnostic tests,

provinces and even hospitals may either find alternative source for these tests or even acquire their own capabilities. This in turn will reduce the number of samples sent to LCDC and increase duplication of laboratory services in the Canadian system.

Identification of other LCDC Products for Cost Recovery

Since the last evaluation, the Health Protection Branch has participated in a "Departmental Cost Recovery and User Fee Study". The study recommended that: 1) HPB review fees levied for current revenue producing items; 2) HPB's Cost Recovery Working Group accelerate its review of HPB's cost recovery efforts; and 3) the Branch provide the Departmental Executive Committee (or another designated body) with regular progress reports. The LCDC was looked at, but its products and services were not considered for further cost recovery by the Branch.

Clients and Stakeholders Opinions

The reactions on the cost recovery question from LCDC's external clients/stakeholders was mixed. About half of the stakeholders felt that the federal government should provide diagnostic and epidemiology services free. They felt that the services provided by LCDC are a part of developing information and coordination in the disease surveillance and control system.

As mentioned in the previous evaluation, many clients would be willing to pay for some laboratory services, others stated that they would rather incur the trouble and expense of developing their own diagnostic services than pay LCDC for what they consider an essential service. Some of those who expressed their willingness to pay also commented that there is a need for improvement in the timeliness of LCDC's services.

Some epidemiologists stated that, if LCDC begins to charge for its services, they would seek LCDC services in epidemiological investigations only if there is an outbreak.

In Conclusion, LCDC charges for one of its publications, namely, Canadian Communicable Disease Report. It also charges a fee for the training course on Bio-Safety. All other LCDC products and services are provided free of charge.

LCDC's cost recovery of CCDR has reduced its ability to reach many of its clients. While, free FAXLINK service appears counter-productive to cost-recovery, it has a better potential for wide dissemination of CCDR.

LCDC's clients consider diagnostic services and other LCDC products to be essential. Therefore, there is some question whether these services and products should be considered for cost-recovery. Any charges for these services and products will have repercussions on the LCDC's efforts to maintain State-of-the-Art "knowledge and expertise" and to retain a central place in the Canadian disease surveillance and control system.

chapter six

findings and conclusions: alternative organizational arrangements

This chapter examines three evaluation questions dealing with: organization of laboratory services within LCDC, mechanisms for keeping laboratories current, and organizational arrangements for LCDC as a whole.

Laboratory Analytical Component of LCDC

The laboratory component of LCDC includes six National Laboratories within LCDC in Ottawa and nine National Centres which are part of provincial public health systems or universities. The National Centres provide, under contract to LCDC, identification services for designated pathogens to public health laboratories. For the provision of these services, the National Centres act just as if they are part of LCDC. National laboratories are fully funded by the federal government while National Centres (currently, with the exception of those in Ontario Public Health Laboratories) receive funds for specific services provided by them and for other special projects which are negotiated with and approved by LCDC.

This section examines and identifies the advantages and disadvantages of the current arrangements and reports on the client satisfaction. For the purpose of discussion in this section, the six national laboratories together with nine National Centres are referred to as the national system of laboratories or the national system. The direct clients of the national system are, generally, the provincial public health laboratories.

The laboratories in the national system are responsible for providing state-of-the-art diagnostic and investigative laboratory services related to infectious diseases and outbreak investigations, and for technology transfer to their clients. They are expected to keep current and maintain themselves at the forefront of new technology. In addition, each laboratory or centre is responsible for the organization of voluntary proficiency testing and quality control of provincial and hospital microbiological laboratories throughout Canada, and for the provision of training in analysis and biotechnology related to the laboratory diagnosis of infectious disease. These training activities range from one-on-one sessions, to seminars, lectures, and national and international workshops on appropriate subjects.

The following advantages and disadvantages were identified as a result of consultations with the managers of laboratories in the national system and its clients.

Advantages:

1. The current system allows for an efficient use of scientific expertise available within and outside LCDC;

2. laboratories which have high volume of specific diagnostic tests can provide the same service to other provinces which do not have sufficient volume to develop their capacity (e.g., rabies in Ontario);

3. participation of laboratories from different parts of Canada provides for networking and facilitates exchanges; and

4. as other expertise becomes available, it is more efficient to designate (if necessary) that expertise as a national centre than to develop parallel expertise in Ottawa.

Disadvantages

1. Capabilities of National Centres varies from centre to centre;

2. not all National Centres have a general budget which causes financial difficulties;

3. some National Centres do not feel that they are a part of the LCDC system because of their geographic isolation from LCDC. They feel that their relationship with LCDC is more at arm's-length;

4. the efforts for the research and development of new technologies within National Centres varies from centre to centre;

5. National laboratories in Ottawa are too distant from patients and patient care. Their service, though rated excellent, can often be late. Some respondents stated that analysis of samples done in Ottawa is often more useful for epidemiology and other monitoring than for primary patient care; and

6. there is a possibility that National Centres which are subject to policies and priorities of their own organizations, could pull out from the national system. Or, expertise at a national centre could move somewhere else. (This was mentioned to have happened but no particulars were given). These factors could leave the national system, at least in the short run, without some necessary services or expertise.

Almost all of the clients of the laboratory services of national laboratories and centres are satisfied with the current arrangements and support them. However, some of them commented on the presence of multiple microbiology laboratories in HPB and that HPB could achieve more scientific benefits by integrating some of them into a single microbiology laboratory. However, this question is not within the terms of reference of the evaluation and is not considered further.

LCDC has closed its clinical biochemistry services since the last evaluation. Almost all respondents stated that this has not caused any undue inconvenience or harm to their work. They all felt that LCDC should not reintroduce clinical biochemistry.

In conclusion, the current arrangement of a mix of national laboratories in LCDC and designated National Centres in provincial public health laboratories and elsewhere works well and has many advantages. Further, the disadvantages have not affected the working of the national system.

LCDC's decision to terminate its services in clinical biochemistry has not caused concerns to its clients.

Mechanisms for Keeping Laboratories Current

The following are some of the mechanisms to keep staff "current" with the latest technologies in their field, which were mentioned during consultations:

1. encouraging staff to participate in in-house training or various government training programs, reading and applying current scientific literature,

2. cross-appointments as university professors,

3. sponsoring and supporting the organization of scientific workshops, technical retraining, peer review, in-house technology transfer, development of leading edge diagnostic/typing methods,

4. interaction/collaboration with universities, networks and the private sector, and

5. conducting scientific research.

Attendance at conferences was also mentioned although international travel budget restrictions prevented support staff from receiving training at international agencies, e.g. CDC, Atlanta.

Respondents felt that even though the contracts between LCDC and the National Centres may not contain specific clauses requiring laboratory personnel to remain current, these professionals remain current through a feeling of professional obligation and to maintain recognition among peers.

LCDC has a program which provides financial and technical support to the National Centres to help them maintain up-to-date knowledge in methodology and to provide training services for their staff to keep current. One of the instruments of this program is research contracts between LCDC and the National Centres for specific assignments for limited periods of time.

Respondents were asked for their comments on the adequacy of current contractual arrangements. Very few respondents were familiar with this subject. And those who were familiar, were equally divided on the adequacy of the contractual arrangements. All respondents expressed the need for assistance and additional funds to help with overhead costs.

Some centres are financed by LCDC in a nominal way (excluding funds for specific research projects). These agencies see their budgets strained.

Four out of the seven contracts with the National Centres are adequate and specific in indicating the responsibilities for maintaining up-to-date knowledge in methodology and training. Of the remaining three, two contracts are also adequate, except there was no mention of training. The third has a very brief "statement of work" and does not mention training.

Other provisions of all seven contracts appear to be adequate to fulfil the objectives of the arrangements.

In conclusion, present mechanisms to keep the system of national laboratories and centres current are adequate. The evaluation, however, has not assessed whether these mechanisms are routinely used or not. To do so would have required a review of the management of external laboratories.

Some contracts with National Centres do not adequately address the issue of keeping current.

Alternative Organizational Arrangements for LCDC

In this section, the evaluation explores the possibility of making LCDC's contribution to the Canadian disease surveillance and control system more effective under a different organizational arrangement.

Evaluation Approach

The evaluation

- identified, for further examination, alternative organizational settings for LCDC,
- made a number of key assumptions in examining the alternatives,
- examined the current organizational setting of LCDC (status quo),
- compared LCDC's current organizational setting with that of the U.S. Centres for Disease Control,
- identified the advantages and disadvantages of alternative arrangements.

Clients and partners of LCDC within and outside Health and Welfare Canada were asked their opinions about the advantages and disadvantages to LCDC and to the Canadian disease surveillance and

control system for different types of organizational arrangements ranging from status quo to LCDC becoming an independent agency.

About 65 external clients were familiar about where does LCDC fit in Health and Welfare Canada, and in particular, in the Health Protection Branch. However, their knowledge about LCDC's place within the Department varied according to their relationship with LCDC; for example, members of ACE and TAC were more knowledgeable than representatives of NGOs. Internal clients and partners of LCDC also offered more concrete comments and suggestions.

In examining the alternatives, the evaluation has taken into consideration the level of the understanding of the clients about the current organizational arrangements of LCDC, and the potential effects of alternatives on the services and products they receive. It was not possible to quantify the responses in most instances.

Alternatives Examined

The evaluation identified six alternative arrangements for LCDC; namely, 1) status quo, 2) LCDC reports directly to the Deputy Minister of HWC, 3) LCDC reports directly to the Minister of HWC, and 4) LCDC becomes a special operating agency (SOA), 5) LCDC becomes a communicable disease institute, and chronic disease epidemiology is moved closer to Health Promotion Directorate, or merged with the proposed Canadian Institute for Health Information, and 6) LCDC becomes an independent agency jointly funded by federal and provincial governments and other sources. In this last scenario, LCDC either becomes a part of the proposed Canadian Institute for Health Information or becomes an agency like the Canadian Coordinating Office for Health Technology Assessment.

Assumptions

In its examination of alternatives, the evaluation assumed that LCDC will continue to:

a) provide current services and products to its partners and stakeholders;
b) provide advice to the Minister of Health and Welfare Canada on matters related to disease surveillance and control;
c) be able to respond to emergencies, outbreaks at the national level and new diseases;
d) retain its leadership role across the country in the areas of disease surveillance and control; and
e) that any alternative arrangements would not compromise the ability of the federal government and HWC to ask LCDC to address important issues of national health concern on an urgent basis.

Those alternatives which violated these assumptions were not considered worth pursuing.

Current Organizational Arrangement of LCDC

The Laboratory Centre for Disease Control is a Directorate of the Health Protection Branch (HPB). The Branch has four program directorates; namely, the Drugs Directorate, the Food Directorate, the Environmental Health Directorate and the Laboratory Centre for Disease Control. In

addition, HPB has a Field Operations Directorate which is mainly responsible for administering the Food and Drugs Act and Regulations.

The objectives of the Health Protection Branch are to identify, advise on, assess and manage "*risks to human health associated with food, drugs, cosmetics, medical devices, radiation emitting devices, other consumer products, and with the man-made and natural environment.*" (Main Estimates, Part III, 1992-93). It also monitors the occurrence and cause of communicable and non-communicable diseases.

All program directorates of HPB, with the exception of LCDC, have a regulatory role. They implement specific pieces of federal legislation. LCDC, on the other hand, administers only one act: namely the Quarantine Act. This it does in collaboration with the Medical Services Branch. As discussed earlier in the report, there is very little ongoing activity in the administration of this Act.

LCDC's primary roles are to develop disease surveillance and control related information and to provide support to the Canadian public health system. With respect to these activities , its direct clients are provincial, hospital and community public health agencies, and universities and other researchers.

By way of contrast, principal clients of the other directorates of HPB include other provincial and community regulators and industry. These directorates maintain information on potential risks of substances and products which come under their purview. Their emphasis is usually on the pre-market evaluation of risks and not on the epidemiology of actual risks.

- With these differences in the orientation and the possibility of conflicts of interest, if LCDC was to be involved in monitoring and evaluating the effects of regulations on health, the question arises: would LCDC be more effective if it were located outside HPB? Or, what are the advantages and disadvantages to both LCDC and the Canadian disease surveillance and control system of different types of organizational arrangements for LCDC?

US Centers for Disease Control and LCDC:

The role of CDC within the U.S. disease surveillance and control system is similar to that of LCDC within the Canadian system. Also the two organizations have similar functions, responsibilities, and programs. While the federal/provincial (federal/state) division of responsibilities in health care and disease control in Canada and USA are not the same, there are many similarities between them. CDC has built a worldwide recognition as a leading disease surveillance and control organization. The evaluation, therefore, compared the organization of CDC within the US federal bureaucracy with that of LCDC within the Canadian context.

In USA, the Centers for Disease Control, the Food and Drug Administration (FDA), Drug Enforcement Agency (DEA), and the Environmental Protection Agency (EPA) are, by and large, responsible for delivering those programs which are delivered by the Health Protection Branch in Canada.

CDC and FDA are part of the "Health and Human Services" portfolio, but independent of each other. The Drug Enforcement Agency and the Environmental Protection Agency are independent of Health and Human Services, and therefore, independent of CDC.

The Drug Enforcement Agency administers US legislation dealing with narcotics and other psychoactive substances. In Canada, the responsibility for administering similar legislation lies with the Bureau of Dangerous Drugs of HPB and its field operations, and law enforcement agencies. Presently, both LCDC and CDC have very little to do with the enforcement of these dangerous drugs.

EPA is outside the health bureaucracy and its programs are designed to protect environment. However, the environment encompasses the wildlife, and regulations which are designed to protect the environment are generally, but not always, beneficial to human health. One of the centers of CDC deals with environmental health.

This independence of CDC from the US regulating agencies ensures that it can objectively examine the effects of these regulations on human health. The evaluation team did not, however, explicitly ask whether the CDC has evaluated the health effects of regulations.

CDC is directly involved in health promotion. Its work groups are organized according to disease entities. Epidemiologists, health promotion experts and laboratory scientists who are working on a disease or disease groups (e.g., TB, sexually transmitted diseases) work together as a team. Officials of CDC commented that this organizational integration ensures that the result of CDC's work is used in health promotion and education.

In HWC, the Health Promotion Directorate (HPD) is a part of the Health and Social Programs Branch and organizationally independent of LCDC. The evaluation observed little interaction between professionals in LCDC and the Health Promotion Directorate.

CDC is independent of federal regulatory agencies. LCDC is a part of the HWC Branch which is responsible for health protection regulations. CDC itself is involved in health promotion. This ensures that the result of its work is used health promotion and education. LCDC is independent of Health Promotion Directorate and there is very little interaction between LCDC and Health Promotion Directorate.

Assessment of Alternatives

The assessment of alternatives included testing each alternative against the five assumptions made (see page 58 - assumptions) opinions of the clients, and the advantages and disadvantages which might accrue under each alternative organizational arrangement.

Status Quo

The Status quo satisfies all five assumptions.

About 60% (40) of the external stakeholders and clients did not see anything wrong with the status quo. They felt that the current organizational arrangements are adequate, and that the perceived conflict of interest is not serious. The weaknesses in the current system (delays in service delivery and poor communication) could be corrected by minor internal adjustments and do not need organizational changes. In general, the external clients thought that the current organizational setting: a) facilitates communication between LCDC and the rest of the Branch; b) allows better evaluation of Branch activities (programs); c) facilitates international contacts; and d) provides HPB with LCDC's expertise and resources to perform its (HPB's) role.

The remaining 40% (25) of the respondents were of the opinion that the present situation is not ideal because of the potential conflict of interest and the perceived lack of flexibility inherent in government departments. They felt that HPB is responsible for designing and implementing regulations. There is a potential for LCDC's independence being compromised under the current reporting relationships. Only 5 of these 25 respondents suggested that LCDC should be a Crown Corporation.

As observed on page 59, under the current organizational arrangement, LCDC is amongst other directorates whose clients are predominantly regulatory agencies and industry. LCDC does not have the visibility and/or proximity to other HWC units which deal with provincial health care and public health agencies. While the current arrangement is satisfactory from the client perspective, there is room for improving LCDC's contribution to the Canadian disease surveillance and control system, if a more suitable alternative organizational arrangement were to be adopted.

LCDC reports directly to the Deputy Minister

This alternative satisfies all five assumptions.

Advantages:

The advantages of this alternative include:

a) the chance of perceived or real conflict of interest arising from LCDC being a part of HPB would be reduced, if not eliminated;

b) LCDC's studies and programs would have better potential for interaction with and influence on health promotion programs, strategic planning and other Departmental programs; and

c) LCDC could serve the entire Department equally. LCDC's departure from the HPB would not adversely affect the programs of either LCDC or HPB. As discussed before, the clients and stakeholders of LCDC are different from those of the rest of HPB.

d) LCDC would be in a more objective position to promote and support the evaluations of health effects of HWC and other federal Departments' regulations and programs.

At present, LCDC and its advisory bodies are too distant from the federal/provincial policy making committees. Proximity to the Deputy Minister would increase the potential contribution that LCDC could make to Canada's public health and health care systems.

Disadvantages:

The main disadvantage of this alternative is that transferring LCDC out of HPB would isolate LCDC laboratories from other HPB laboratories. This would make collaboration between laboratories that much more difficult. A counter argument to this line of thinking is that the LCDC laboratories mainly provide support to the provincial public health systems and analyze samples from patients. On the other hand, other HPB laboratories analyze samples of substances they regulate.

Many of the respondents felt that this alternative would resolve the perceived problem of conflict of interest and LCDC could possibly operate in a more independent fashion. However, a few of the respondents contended that this alternative does not address the previously mentioned real problems facing the current system (e.g. delays in LCDC service etc.); and does very little to enhance the Program's image among its partners and stakeholders.

This alternative appears to be the most preferred among those respondents asking for organizational change. It keeps LCDC within Health and Welfare and at the same time increases its visibility to the policy makers of the federal/provincial health care and disease surveillance and control system. The alternative also comes closer to CDC's organizational location in the U.S. federal bureaucracy and might provide the independence needed for supporting the evaluations of the effects of federal regulations on the health of Canadians.

LCDC reports directly to the Minister

This alternative satisfies all the five assumptions. However, under this alternative, the Department may have to work through the Minister's office to access LCDC, and vice versa.

Advantages:

There are two advantages of this alternative, a) LCDC's visibility and influence within Canada's public health system would increase, and b) LCDC would also have more independence in carrying out its programs.

A few of the respondents, among those who asked for an organizational change, felt that this alternative would resolve the potential for conflict of interest; enhance the Program's image among partners and stakeholders; provide the Program with more psychological and professional leverage; allow LCDC management more flexibility and freedom of action for quick response to emergencies; improve the program delivery to the provinces; and create an arms-length relationship with HPB and HWC. However, these respondents felt that the Program would still be required to operate under government regulations and routines.

Disadvantages:

The disadvantages of this alternative include:

a) LCDC, being independent of HWC and reporting directly to the Minister, would reduce the links between LCDC and the rest of HWC;

b) undertaking of joint programs with other branches of HWC would be very difficult, if not impossible;

c) LCDC could not count on backup provided by rest of the Department, and by HPB in particular, and in the same vein, LCDC's expertise would be lost to HWC or have to be duplicated by HWC;

d) LCDC may turn out to be an advisory body and be more "politicized" rather than remain professional;

e) priorities for LCDC programs could be more subject to interest group pressures than if it was at arms- length from the political apparatus; and

f) links between LCDC and its provincial clients and partners would have to be at the Ministerial level, the cooperation between LCDC and its partners may be affected by federal/provincial relations, and LCDC would have to tread very carefully when advising provincial ministries.

Incremental benefits of LCDC reporting directly to the Minister over it reporting to the Deputy Minister are very small when compared with the potential for it becoming ineffective.

LCDC becomes a special operating agency

This alternative meets the five assumptions provided that the charter, the role and the responsibilities of the special operating agency explicitly includes the essence of the assumptions.

According to the publications provided by the Treasury Board Secretariat and Consulting and Audit Canada, Supply and Services Canada, a Special Operating Agency is a manageable, self-contained unit within a government department that has a clearly defined set of outputs and operates under a specific, tailored agreement negotiated between the Agency, the parent Department and the Treasury Board. This agreement provides the Agency with increased delegation and management flexibility.

Criteria for potential agencies are:

1. that they be discrete units of sufficient size to justify changes;
2. that they be wholly concerned with the delivery of services to the public, to the private sector, or to government;

3. that they can be held independently accountable within the parent department; and
4. that day-to-day involvement of the Minister is unlikely.

Special operating agencies are considered to be similar to private sector organizations and expected (after an initial period of establishing itself) to generate revenues to meet its costs.

LCDC meets the four criteria of a special operating agency. Under this alternative, LCDC would have to recover costs for its products and services from its clients. However, as stated before, most of LCDC's clients felt that its services and products are essential and should be free. Furthermore, if LCDC begins charging for its products and services, provinces may charge LCDC for samples and information they provide to it. Some large provinces may establish their own capabilities, weakening LCDC's viability. This in turn will affect the smaller provinces and create unnecessary duplication within the Canadian disease surveillance and control system. And more importantly, an independent agency will not be able to negotiate or speak on behalf of the Department, and consequently, LCDC's coordination role will erode over time. A counter argument to this is that the provinces and other stakeholders will continue to work with LCDC realizing that they will have to bear additional costs if LCDC becomes unable to provide the required services.

Advantages:

Consultations with stakeholders identified the following advantages:

a) More delegation of authority and responsibility to LCDC;

b) more flexible work procedures;

c) more opportunity for applying the best private and public sector management techniques;

d) better and faster response to requests for services;

e) faster adaptability to the changing needs of stakeholders and partners; and

f) elimination or avoidance of the risk of conflict of interest that results from having LCDC (an advisory agent), being part of HPB (a regulatory agent).

Some of the respondents also added that a national agency which has the responsibility for gathering information should not report to an agency which uses the information to regulate, so that the regulatory agency would not be seen to be manipulating the information and the information collection.

Disadvantages:

The respondents cited two disadvantages, the responsibility of and difficulties in having to secure financial resources, and problems arising during the transition from one organizational structure to another.

While the majority of respondents were in favour of the status quo, those in favour of organizational changes preferred that LCDC report directly either to the Deputy Minister.

As the rules governing special operating agencies evolve, this alternative may look more attractive than it does at present. In particular, if continued funding is guaranteed and the cost recovery is not expected, LCDC could very well operate effectively as a special operating agency. However, under the present rules and expectations governing SOAs, this alternative is not viable.

LCDC becomes a communicable disease institute

This alternative does not address the basic evaluation question about location of LCDC. Consequently, it was not considered any further within the context of LCDC's organizational arrangement.

However, the options of bringing the Bureau of Chronic Disease organizationally closer to the Health Promotion Directorate or merging the Bureau with the proposed Canadian Institute for Health Information do merit consideration because (as discussed earlier) the main users of information developed by the Bureau of Chronic Disease Epidemiology are health promotion professionals, researchers, primary health care workers and regulators. Moreover, the argument becomes stronger if the Bureau's program is predominantly that of information collection and if the analysis of information does not require any skills which are not available in the health promotion area or a statistical/information agency.

On the other hand, if the Bureau's program includes a strong and significant component of risk assessment and/or field epidemiology investigations, then it does not make any sense to move it farther away from other field epidemiologists in the Department. The evaluation found that the Bureau is very active in risk assessment; for example, *Childhood Cancer Control Programs, childhood asthma risk assessment, Canadian Farm Operator Mortality Study*, etc. These studies require knowledge beyond what is normally available to statistical or data gathering agencies.

Alternatives to moving the Bureau of Chronic Disease Epidemiology out of LCDC, are either to move the Health Promotion Directorate to LCDC or to improve communication between LCDC and the Health Promotion Directorate. Either of these actions would improve the usefulness of the result of LCDC's work.

LCDC becomes an independent agency with multiple funding sources

This alternative does not meet the assumptions b) and e) (see page 58 - assumptions). An independent agency will have to depend on many financial sources. It can not be expected to treat one source above the others. In cases where the advice provides more benefits to one client than to others, its integrity could be called into question. Also, the programs of LCDC would then be subject to approval from a board of Directors representing its broad base clients. This will reduce the ability

of the federal government and HWC to ask LCDC to conduct specific studies on an urgent basis. This alternative is, therefore, not considered any further.

Alternatives Worth Pursuing

LCDC is providing satisfactory service and products under the current organizational setting. The status quo is acceptable to a majority of LCDC's clients who were consulted. However, a majority among those who asked for a change, favoured the alternative where LCDC reports directly to the Deputy Minister. The evaluation also identified many advantages of this alternative.

LCDC's reporting directly to the Minister of Health and Welfare Canada appealed to some of those who asked for a change. However, the assessment revealed that the benefit of this alternative over the alternative of LCDC reporting to the Deputy Minister of Health and Welfare Canada were marginal, and at the same time, the potential for LCDC becoming ineffective significant.

The requirement for becoming financially independent may adversely affect LCDC's program and effectiveness if it were to become a special operating agency. Under the current rules governing special operating agencies, this alternative is not viable.

In conclusion, while the status quo is satisfactory, the alternative of LCDC reporting to the Deputy Minister merits further consideration to enhance the effectiveness of LCDC's contribution to the Canadian disease surveillance and control system. Also, better communication between the Health Promotion Directorate and LCDC would ensure that the results of LCDC's work are used in health promotion programs.

Appendices:

A. Evaluation Questions
B. Statistical Tables
C. Charts and Graphs
D. Case Studies

appendix A

EVALUATION QUESTIONS
EVALUATION OF LABORATORY CENTRE FOR DISEASE CONTROL
HEALTH PROTECTION BRANCH

The evaluation of LCDC will address the following 18 questions covering seven general issues: the role of LCDC, the extent to which LCDC fulfils the expectations of its clients and partners, technology transfer, cost-recovery, alternative organizational arrangements, risk assessment, and the relevance and the quality of expertise and services provided to clients and partners, and the level of expertise developed and maintained by LCDC:

1. What is an ideal role for LCDC, given the current provincial and federal mandates in disease surveillance and control?

2. What role should LCDC play in the development of risk assessment and management for the disease surveillance and control system?

3. How consistent is LCDC's current role with the "ideal' role?

4. What gaps exist in the system?

5. What modifications to LCDC's role are necessary to eliminate gaps and unnecessary overlaps in Canada's disease surveillance/control system?

6. What are the expectations of clients and partners (stakeholders)?

7. How consistent are the expectations with the LCDC's current and ideal roles?

8. What types of resources are necessary for LCDC to fulfil these expectations?

9. How and to what extent does LCDC fulfil it's mandate and the expectations of its clients/stakeholders?

10. What processes and technology (commercially exploitable as well as non-exploitable) has LCDC developed in the last five(5) years which can be transferred to the public or private sectors?

11. What efforts has LCDC made in transferring the technology and how successful has it been in doing so?

12. What additional mechanisms should LCDC design and implement to transfer such processes and technologies in the future?

13. What efforts has LCDC made in cost-recovery in the areas suggested by the last evaluation?

14. What are the results and consequences of these efforts?

15. What further products and services are possible candidates for cost-recovery given the potential for ensuing liabilities?

16. What are the advantages and disadvantages to LCDC and the disease surveillance/control system from different types of organizational arrangements ranging from the status quo to an independent agency?

17. What are the advantages and disadvantages to LCDC and the disease surveillance/control system of different types of organizational arrangements as far as the laboratory analytical component is concerned?

18. What mechanisms should be in place to maintain the system of National Laboratories and Centres current and in the forefront of expertise?

DISEASE SURVEILLANCE AND CONTROL SYSTEM
A Generic Model
EVALUATION OF LABORATORY CENTRE FOR DISEASE CONTROL
HEALTH PROTECTION BRANCH

Dr. Rama C. Nair of the University of Ottawa was commisioned to develop, for the purpose of the evaluation, a generic model for a system for disease control and surveillance. Dr.Nair presented the results of his work in the report entitled " System for Disease Control and Surveillance - A Generic Model." Key findings and conclusions are summarized as follow:

Key findings and Conclusions

The system of surveillance and control of diseases and their risk factors is composed of several specific tasks, interrelated to each other. The primary purpose of a system of disease control and surveillance is to reduce the burden of illness on the population. The system is more than a health care model. It includes the modern definition of health, recognizes the contribution of traditionally non-health oriented organizations (e.g., police, transportation) to the health of individuals and the society, and incorporates the surveillance and control of related factors to preserve the health of the people.

For the system to be effective, there needs to an efficient communication between various players in the system. Information exchange is, therefore, one of the essential ingredients of the system. It is imperative that a national agency be identified to coordinate this activity.

Existence of central databases is crucial to the success of the system. This would allow a National perspective on the incidence of disease and/or risk factor and allow for the detection of diseases before they become a major problem. In particular, without a central system for data analysis, epidemics or beginning of epidemics of diseases with low incidence would go unnoticed for a long time.

In addition to the central collection of data, the coordination of research into the causes and treatment of diseases and rehabilitation at the national level are also important. This national level coordination will help identify areas of specific needs, directed to specific sub-groups of the population which might have a disproportionately higher burden of illness, and will contribute to the achievement "Health for All."

Health Promotion activities will play increasing role in the surveillance and control system in the future, moving away from the current emphasis on the curative aspects.

appendix C

EXECUTIVE SUMMARY
ROY A. ANDERSON & ASSOCIATES REPORT
EVALUATION OF LABORATORY CENTRE FOR DISEASE CONTROL
HEALTH PROTECTION BRANCH

This appendix is a reproduction of the executive summary of the report produced by Roy A. Anderson Associates for the evaluation.

EXECUTIVE SUMMARY

The Laboratory Centre for Disease Control

The Laboratory Centre for Disease Control (LCDC) was established in 1919 under the Health and Welfare Act as the Bureau of Hygiene. Since its establishment, LCDC has been subject of several modifications, the last of which took place in response to recommendations in a 1984-85 study resulting in: a) the elimination of the Bureau of Medical Biochemistry, Infection Control, and Tobacco and Biometrics; b) the creation of the Division of Biosafety; c) the reorganization of the Bureau of Epidemiology into two separate bureaux; the Bureau of Chronic Disease Epidemiology and the Bureau of Communicable Disease Epidemiology and d) the establishment of the Risk Management/Strategic Planning Unit.

This evaluation was designed to examine: LCDC's current role in health protection; to establish whether the services delivered to its stakeholders and partners meet their expectations; the extent to which LCDC has succeeded in transferring technology to other sectors; the possibilities of implementing cost recovery options; LCDC's role in risk assessment; and alternative organizational arrangements.

Mission and Organizational Structure

To carry out its mission as the national centre for the identification, investigation, control, and prevention of human disease, LCDC has structured its operations around four bureaux: the Bureau of

Communicable Disease Epidemiology, the Bureau of Chronic Epidemiology, the Bureau of Microbiology, and Bureau of HIV and HTLV Laboratories and Research. Additionally there are four program support units reporting directly to the Director General of LCDC: Risk Management/Strategic Planning Unit, Administration, Finance and Personnel, the Division of Biometrics and the Division of Biosafety. LCDC also provides financial support to the work of four advisory committees: the Advisory Committee on Epidemiology (ACE), The Committee to Advise on Tropical Medicine and Travel (CATMAT), the Technical Advisory Committee (TAC), and the National Advisory Committee on Immunization (NACI).

Functions and Services

The Bureau of Communicable Disease Epidemiology conducts national surveillance and other special studies in infectious diseases, in addition to undertaking outbreak investigations.

The Bureau of Chronic Disease Epidemiology monitors and analyzes Canada's vital and health statistics, and publishes reports on patterns of disease, hospitalization, injury, and death.

The Bureau of Microbiology provides provincial public health laboratories and tertiary care hospitals with diagnostics and laboratory services related to infectious disease. These services are provided through six National Laboratories located in Ottawa and nine National Centres in the provinces.

The Bureau of HIV and HTLV Laboratories and Research provides Canadian laboratories with national diagnostic and expert reference laboratory for HIV and HTLV I and II. (The National AIDS Program will not be dealt with in this evaluation).

The Office of Biosafety provides national advisory service on safety in microbiology laboratories and in hospitals and data on laboratory-acquired infections and accidents. [1]

The Division of Biometrics supports LCDC computer services and biostatistical expertise. The Risk Management/Strategic Planning Unit supports LCDC's role in identification, assessment, and management of health risks to the Canadian public.

Services Provided by LCDC Within Its Current Role:

Influencing Health Policy: LCDC interprets epidemiological data findings from a national perspective, producing public health strategies and policy recommendations. It carries out and actively participates in national epidemiological surveys and applied research studies. LCDC also provides public health and clinical laboratory services and expertise which complement and support existing provincial activities.

Health protection through Risk Management: LCDC carries out hazard identification by risk assessment through disease surveillance and investigation and applied research for the development of appropriate strategies for managing risk.

Outbreak Investigation: This function involves epidemiological work. LCDC investigates and isolates the causes of disease outbreaks. The national public health laboratory network in LCDC provides positive identification of disease-causing microorganisms.

Leading Edge Technology Development and Transfer: High technology laboratory techniques such as 'fingerprinting' of infectious diseases, epidemiological investigations of new diseases, and new biotechnological processes are often developed and used by LCDC. These developments are offered and transferred to other public health laboratories or the private sector.

LCDC findings are disseminated through regular publications, special reports, and its four advisory committees.

Training and Education: LCDC provides a national service of postgraduate training in applied public health investigation (microbiology and epidemiology).

International Liaison: LCDC is a WHO Collaborating Centre for such activities as Biosafety and Biocontainment Technology and for specific diseases such as tuberculosis, influenza, and gonorrhoea. LCDC also collaborates in major studies with the Pan American Health Organization (PAHO) Tuberculosis Study Centre for the Americas.

Quality Assurance: LCDC shares with the provinces the responsibility for quality assurance of public health laboratory services. At LCDC, quality assurance programs evaluate public health laboratory services provided by provincial public health laboratories and tertiary care hospital laboratories. LCDC established the gold-standard laboratory reference procedures and maintains laboratory biosafety standards for the practice of diagnostic microbiology. [1]

Quality of Services and Value to Respondents

Not all respondents were familiar with all 18 issues, therefore response rate on each question varies.

All stakeholders consulted stated that as recipients of LCDC's services, the Centre is of great value to them in carrying out their responsibilities. They also identified special unique services for which they depend entirely on LCDC, such as: national coordination, investigative research in health problems, diagnostic research, and proficiency testing. While the majority of stakeholders have expressed

their satisfaction with the quality of the services, complaints about delays in delivering some services such as publications, test results, and data analysis, were voiced by about 60% of the respondents consulted on this issue.

Ideal Role and Expected Services

Ideally, stakeholders expect LCDC to provide the following types of services: i) services of a general nature repeatedly requested by numerous respondents; ii) specific services dealing with isolated problems; and iii) unique services. These include:

i) Services of a General Nature : Maintain a national focus for surveillance; maintain a national picture and international intelligence; maintain a common data bank; take a more active role in epidemiology; enhance training; adopt a greater leadership role; conduct more research; set standards and ensure that data is more uniformly collected; provide more information to the field; ensure more communications [?]; and expand publications.

ii) Specific Services: Provide more funding for diagnostic kit testing; provide more funding for local projects on data collections; increase THE NUMBER OF positions of Field Epidemiologists in smaller provinces; provide more involvement to work in outbreak support; strengthen role as epidemiological/statistical watchdog; provide validation for surveillance for 10-15 prominent diseases; establish feedback loops with injury data; introduce behavioral data; develop mechanism for TB; and create a higher profile for the advisory committees.

iii) Unique Services: Diagnostic microbiology; reference typing, proficiency testing, surveillance data, disease control advisory services, and biosafety advisory and consulting services.

The evaluation recognized from the respondents' responses, that while respondents appreciate very much the value and magnitude of services provided by LCDC and their impact upon the entire Canadian health protection system, nevertheless, in general, they expect LCDC to "do what they do now, only better," in terms of faster service, more in depth data analysis, and more proactive leadership in health promotion, (as LCDC a national institution).

Consistency Between Current and Ideal Role

The Canadian Disease Surveillance/Control System Model depicts a realistic representation of the actual flow of medical information and the interaction taking place among those bodies involved with the process of medical information management.

All LCDC activities appear to be consistent with its mandate.

There is a lack of understanding among a minority of stakeholders regarding the basic organizational structure of the four Bureaux.

In most instances, respondents who were conferred with on the issue of ideal role equate the ideal role for LCDC with "doing what they are doing now, only better."

Gaps and Overlaps

Gaps in the services provided by LCDC are not significant enough to require any drastic action on the part of management. In most cases were respondents cited "gaps" in LCDC services, the emphasis was on the need for a more specific service, more in-depth data analysis, and more effective coordination.

Real gaps (i.e. desirable services that are not delivered by LCDC), are few in number and are confined to small pockets in the health system, i.e. typing of pathogens like B. cereus and Cl. perfringens.

The issue of overlaps and duplication does not appear to be of great significance, as only very few cases of federal/provincial interaction in the health system are perceived as duplications.

Generally speaking, LCDC is currently effective in providing a vast number of services that respondents would ideally expect. However, efficiency may not be meeting stakeholders expectations, e.g. slow response to requests.

New services should be delivered by LCDC, such as: developing national standards for reporting mortality and morbidity; developing criteria for validation of data; and conducting risk factor surveys.

Expectations

Among improvements needed respondents cited: faster response to requests for service or advice; more proactive leadership in health promotion; improved lines of communication with the provinces; and more special studies.

Resources

Increased resources may be required in order to meet client expectations, e.g. increased number of field epidemiologist and better surveillance activities.

Risk Assessment

With respect to the issue of risk assessment, the stakeholders' responses indicated that most are not familiar with LCDC's role in this area. Some of those knowledgeable in this area, questioned whether LCDC should even be involved in this activity, while others recommended special initiatives such as conducting more studies on the population to determine risks associated with the use of some

vaccines, and examining levels of harmful substances in the environment.

Alternative Organizational Arrangements

The evaluation examined two aspects of organizational arrangements. The first aspect involves organization of laboratory support with regard to the National Laboratories and some National Centres under provincial jurisdiction. The second aspect deals with advantages and disadvantages of various types of organizational arrangements for LCDC that would permit a fine tuning of LCDC's responsibilities, programs, and priorities in light of its role in the health care system.

The investigation into alternative organizational arrangements responded to the March 1991 planning document prepared for LCDC which recommended that "renewed efforts be made to have LCDC operate under a more suitable structure such as a Crown Corporation, a National Institute, or a Special Operating Agency."

With respect to the operations in the National Laboratories and National Centres, almost all respondents were of the opinion that the current system is the most suitable way of providing microbiological services, however they believe that HPB could achieve scientific benefit by integrating some of its microbiology laboratory services into a single laboratory. The majority were also in favour of not adding a clinical biochemistry laboratory to LCDC present operations. Half of those consulted were in favour of having all LCDC microbiology laboratory services provided by National Centres, universities or hospitals. The other half were against the idea.

To examine and evaluate the advantages and disadvantages of various types of organizational arrangements for LCDC, respondents were consulted and the option of a Special Operating Agency was reviewed. Consultations revealed that the current organizational status of LCDC is satisfactory to 60% of those stakeholders who were asked to consider this issue. 32% of the respondents who were asked to consider this issue were in favour of LCDC operating in an arms-length relationship with the Department, taking the shape of a special branch reporting directly to the Minister or the Deputy Minister.

The Special Operating Agency concept was not recommended as an option for two reasons; a) the almost unanimous rejection by the stakeholders of the cost recovery principle, thus depriving the an Agency from crucial financial resources and b) only 8% of those consulted on this issue supported Special Operating Agency option.

Contractual Arrangements with National Laboratories

Contractual arrangements are established between LCDC and National Centres concerning the delivery of certain services. This evaluation examined these contractual arrangements in terms of inclusion of clauses pertaining to lab personnel keeping current in knowledge and in the forefront of expertise.

Examining a sample of contracts revealed that they are adequately prepared to achieve LCDC's targets with some exceptions where stipulation for training was not mentioned.

Keeping Current

No areas of specific weakness were identified with regard to mechanisms that should be in place to maintain the system of National Laboratories and Centres current and in the forefront of expertise. The evaluation did not identify any new mechanisms to be introduced into the current system as the present mechanisms are already comprehensive.

Mechanisms are in place to keep National Laboratories and Centres current, e.g. to encourage staff to participate in in-house training or various government training programs, reading and applying current scientific literature, cross-appointments as university professors, sponsoring and supporting the organization of scientific workshops, technical retraining, peer review, in-house technology transfer, development of leading edge diagnostic/typing methods, interaction/collaboration with universities, networks and the private sector, and conducting scientific research.

If such mechanisms are properly adhered to the objectives of "keeping current" should be adequately met. As a longitudinal assessment of the level of knowledge and expertise of lab personnel was not undertaken, no conclusion has been drawn to judge whether mechanisms to "keep current" have been adequately implemented or if they are effective.

1.. The Role of LCDC in Biosafety - A Case Study, Appendix C.

2.. A Strategic Plan for the Bureau of Chronic Disease Epidemiology, Health and Welfare Canada, March 1991.

appendix D

SUMMARY OF CASE STUDIES
EVALUATION OF LABORATORY CENTRE FOR DISEASE CONTROL
HEALTH PROTECTION BRANCH

Five case studies were conducted during the course of evaluation to examine the role of LCDC and the impact of LCDC's activities on the Canadian disease surveillance and control system. The case studies were:

1. Domoic Acid Food Poisoning,
2. Food-Borne Infections,
3. Office of Bio-Safety,
4. Children's Hospital Injury Reporting and Prevention Program, and
5. Tuberculosis.

Tuberculosis case study was conducted in-house by the Program Evaluation Division of the Program Audit and Review Directorate. The other four studies were conducted by the Roy A. Anderson Associates.

This appendix presents the conclusions of the five case studies.

1. Role of LCDC in Domoic Acid Food Poisoning: Conclusions

The domoic acid episode shows that the Canadian public health system can respond to challenges of investigating unrecognized diseases. In this case, the cooperative efforts of the Canadian regulatory, public health, and scientific systems resulted in the identification of domoic acid - the disease causing agent - and the design of a surveillance / control system to protect the mussel industry and the consumer.

Normally, LCDC's role in the investigation is that of conducting field epidemiological investigation, carry out laboratory analysis, coordinating efforts (in particular, where more than one province is involved) for the control of the outbreak and contributing to the prevention of outbreaks.

In the domoic acid episode of 1987, LCDC contributed to the outbreak investigation in most of these areas. Specifically, LCDC conducted field epidemiological investigations which confirmed the mussels as the potential source of the disease. It coordinated the information flow between different laboratories and the field immediately after the outbreak. LCDC played a significant role as an

epidemiological advisor. Subsequently it brought together scientists from various participating agencies for a symposium on domoic acid toxicity and produced a comprehensive publication on this outbreak. This publication remains a major scientific reference on domoic acid food poisoning.

LCDC field epidemiologist and the advisory staff were quite alert and established their lead role in identifying mussel as the source of the outbreak. The quality of their services in coordination of information and its publication was also quite satisfactory. However, biochemical investigations were not possible due to lack of proper facilities, expertise, and availability of clinical samples. LCDC activities in domoic acid food poisoning were consistent with its role and mandate.

2. Role of LCDC in Food-borne Infections

LCDC actively participates, when requested, in outbreaks of food-borne illnesses. It has contributed to research in the causes and epidemiological progression of food related illnesses. Laboratory and epidemiological research , and surveillance information produced by LCDC has contributed to federal food regulations and standards as well as in guidelines for food handling. When required, LCDC has actively participated in public health education.

Present services provided by national centres and laboratories are considered satisfactory by all provincial authorities. Currently, reference and typing services provided by the LCDC laboratory cover most microorganisms. However, national centres could be established for typing of organism such as Hepatitis virus, Bacillus Cereus and Clostridium Perfringens. Also, modified PCR protocols for detection of verotoxigenic E. Coli in food could be used to detect this organism in faeces and blood samples.

3. The Role of LCDC in Biosafety

The Office of Biosafety (OBS) contributes to the Canadian disease surveillance and control system by providing advice on training in biosafety issues. The activities of OBS are consistent with the mandate of LCDC. There is need to periodically review the usefulness of the OBS's bibliographic reference service, given other sources for such information and easy access to them. There is a need to examine the desirability to have a unified approach for the development of material safety data sheets related to human, animal, and plant pathogens in Canada.

4. The Canadian Hospitals Injury Reporting and Prevention Program (CHIRPP)

The consultation participants who were familiar with CHIRPP were quite positive about it and its potential. The areas which required improvement consisted of:

- the need for regular feedback to the participating hospitals and other users in the form of bulletins or newsletters;

- the need for program visibility, i.e. a strong local presence representing the program;
- the need to brief new personnel involved in the program; and
- the need to identify the formal and informal networks of agencies involved in child injuries and prevention.

CHIRPP appears to be in its infancy in terms of its collection and analysis of data and in its networking of the potential users of the database. Work should be put into streamlining the data collection process and in providing feedback to the users and potential users of the system.

LCDC appears to be the best coordinating body for CHIRPP. While there are concerns about the communication, access to and use of CHIRPP information, no better alternative has been identified to provide this needed service.

5. **Tuberculosis**

As one of the key players in the surveillance and control of TB, LCDC has a and is fulfilling its role. This role is also consistent with the mandate and role of LCDC.

> LCDC is recognized at the national and international level as the national laboratory centre in the surveillance and control of TB in Canada.
>
> In anticipation to a TB outbreak in Canada similar to the United States. LCDC epidemiological activities on TB have reacted timely to recent public and media interest in the re-emergence of TB in the US.

LCDC epidemiological activities, however, are viewed as "recent" due to lack of continuity. High staff turnover in LCDC is regarded as the main cause for the lack of continuity of certain epidemiological activities.

LCDC shares the surveillance and control of TB with other key players and must work in close cooperation with them. LCDC shares the national surveillance of TB data with Statistics Canada, to take on Statistics Canada TB surveillance activities, to make them part of the "National Notifiable Disease System", LCDC needs to continue further consultations with the provinces.

To continue to have a meaningful and active role in the surveillance and control of TB LCDC needs to work in close cooperation with the provinces and territories and other key players. LCDC needs to maintain and develop links not only with ACE members but also with provincial and territorial TB control directors, particularly with those in western provinces. Without the cooperation of the other key players, LCDC, for example, would have a limited role in the surveillance and control of TB among natives and setting national standards for tuberculosis. In summary, **LCDC's role in the surveillance and control of TB is to support provincial/local and territorial public health authorities in the identification, control and prevention of TB in Canada.**

Appendix E

RECOMMENDATIONS OF THE 1984-85 LCDC EVALUATION
EVALUATION OF LABORATORY CENTRE FOR DISEASE CONTROL
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This appendix lists recommendations of the last program evaluation and summarizes major findings and conclusions of five other external reviews of LCDC.

I. PROGRAM EVALUATION LCDC: 1984-85

The evaluation was conducted by the Program Audit and Review Directorate. It made the following 21 recommendations:

Recommendations

1. That the mandate of LCDC's be clarified and strengthened in terms of its leadership, support and service roles in the area of laboratory services and communicable diseases.

2. That the department confirm and clarify LCDC roles and responsibilities in non-communicable diseases.

3. That LCDC conduct and report on a review of the Advisory Committee on Epidemiology, Laboratory Services, and Immunization. The review should include an examination of the committees' mandates, continued relevance, achievements and reporting relationships; and

4. That LCDC develop and implement a strategy for its communications and work interactions with other Health and Welfare branches, the Health Division of Statistics Canada, and other federal departments, in order to improve mutual understanding of, and service to, each others needs.

5. That responsibility for policy, planning and administration of the Quarantine Act (and probably Regulatory Health Services) and its activities be transferred to LCDC;

6. That due to the speed and nature of international travel which has resulted in port-of-entry interception of diseases becoming less and less likely, the inspection activities be the subject of review to determine their effectiveness and the appropriate level of resources required to carry them out, as well as their appropriate location.

7. That the existing port-of-entry inspection and surveillance activities continue to be performed by Medical Services Branch staff until the recommended review has been carried out.

8. That the following services be considered as potential candidates for cost recovery:

   a) Diagnostic reagents
   b) Laboratory proficiency surveys;
   c) Evaluation of laboratory equipment and of medical devices;
   d) Training; and
   e) Assistance to manufacturers of laboratory equipment.

9. That LCDC continue to develop new reagents that are required, but for which there is low volume of production;

10. That LCDC transfer the reagent production to provincial or private laboratories when the technology and know-how are established; and

11. That LCDC recover at least the incremental cost (in additional material and staff time) incurred in producing reagents.

12. That LCDC explore with the Technical Advisory Committee the viability of withdrawing from the direct operation of proficiency testing programs and restricting its activities to the provision of sera to provincially operated programs, or

13. Continuing operating proficiency testing programs but under contract with the provinces, thus recovering costs from the individual participating laboratories.

14. That activities with respect to tobacco and alcohol be limited to laboratory study and epidemiological surveillance, and that policy development activities related to tobacco control be the responsibility of PP&I in conjunction with the Environmental Health Directorate and the Health Services and Promotion Branch;

15. That the Drug Adverse Reactions and Product Related Diseases information system be recognized as an integral part of the LCDC mandate and be enhanced as a national program and as part of the post-market surveillance program on drugs and other products;

16. That surveillance and epidemiology functions be organizationally concentrated by combining Tobacco Control and Biometrics, Epidemiology, and Infection Control into one Bureau, an action which would proyide costs savings and more flexibility in the deployment of resources;

17. That an internal information system be established to capture data on the volume of services provided along with the cost of providing them;

18. That LCDC be considered primarily a development agency whose aim it is to provide support to the provinces and the Department, to develop new methodologies, work at the forefront of diagnostic methodologies with the view of helping the provinces use the methodology once it is firmly established.

19. That specific criteria and performance goals be established for each activity (e.g. Field Epidemiology Program, Infection Control, reagent production etc.) and that once the goal is reached or the knowledge or technical base developed, the activity be transferred to the provinces or other agencies whenever feasible;

20. That LCDC take leadership in working with the provinces to improve the collection and dissemination of surveillance data and that a more effective communication system, perhaps using computer technology, be established for more timely information exchange on disease control and surveillance; and

21. That there be no further cuts in LCDC resources until the mandate and responsibilities of the organization have been confirmed.

II. MAJOR FINDINGS AND CONCLUSIONS OF EXTERNAL REVIEWS

There were five external reviews of LCDC.

1. External Review, Cancer Section, Bureau of Chronic Diseases, Laboratory Centre for Disease Control, F. White (Chairman, Review Committee), (April 1991).

2. A Strategic Plan for the Bureau of Chronic Disease Epidemiology, Laboratory Centre for Disease Control, Communication Management Consultants, Pakenham, Ontario, K0A 2X0. (March 1991).

3. Review of the National Laboratory for STDs at LCDC performed by R.C. Brunham, (November 1990).

4. External Evaluation of the National Laboratory for Sexually Transmitted Diseases, Laboratory Centre for Disease Control, Ottawa, Ontario prepared by W.L. Albritton, University of Alberta, Edmonton, Alberta, (April 1991).

5. Communication Strategy: Consultation with Public Health Professionals, Neima Langner, (August 1992).

1. External Review, Cancer Section, Bureau of Chronic Diseases: 1991.

The purpose of this review was to address the relevance of the work being done by the Cancer Section , Bureau of Chronic Diseases of LCDC, its quality, productivity, and management. The report identified strengths, impediments, and Green Plan issues. The report recommended that: the Chronic Disease not only continue steady development but to more firmly establish the mandate of the Chronic Disease Epidemiology group within the Branch and the Department; give greater attention to the marketing of the unit; increase the core budget; further develop the strategic planing process within the unit; development of a written mission statement; and an infuse senior administrative support staff familiar with the requirements of grant and contract management.